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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1987

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

NINETY-NINTH CONGRESS

SECOND SESSION

ON

H.R. 5233

AN ACT MAKING APPROPRIATIONS FOR THE DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES, FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 1987, AND FOR OTHER PURPOSES

PART 2—(Pages 1-1255)

Department of Health and Human Services

Printed for the use of the Committee on Appropriations

U.S. GOVERNMENT PRINTING OFFICE

57-852 O WASHINGTON : 1986

For sale by the Superintendent of Documents, Congressional Sales Office
U.S. Government Printing Office, Washington, DC 20402

S181-55

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CONTENTS

TUESDAY, MARCH 4, 1986

Page

Department of Health and Human Services: Office of the Secretary 1

WEDNESDAY, MARCH 5, 1986

Department of Health and Human Services:
National Institutes of Health 93
National Cancer Institute 147
National Institute of Allergy and Infectious Diseases 215

THURSDAY, MARCH 6, 1986

Department of Health and Human Services:
National Institutes of Health:
National Institute on Aging 247
Division of Research Resources 289
National Institute of Dental Research 313

TUESDAY, MARCH 11, 1986

Department of Health and Human Services:
National Institutes of Health:
National Institute of Neurological and Communicative Disorders and Stroke 345
National Eye Institute 385
National Institute of Environmental Health Sciences 409
John E. Fogarty International Center for Advanced Study in the Health Sciences 431
National Library of Medicine 447
Office of the Director 471
Buildings and Facilities 471

WEDNESDAY, MARCH 12, 1986

Department of Health and Human Services:
Health Resources and Services Administration 493
Office of Assistant Secretary for Health 523
National Institutes of Health 611
National Institute of Diabetes, and Digestive and Kidney Diseases 615
National Institute of Arthritis and Musculoskeletal and Skin Diseases 647
National Heart, Lung, and Blood Institute 669
National Institute of General Medical Sciences 701
National Institute of Child Health and Human Development 723

THURSDAY, MARCH 13, 1986

Department of Health and Human Services: Page
Office of the Inspector General 747
Office for Civil Rights 771
Centers for Disease Control 783
Alcohol, Drug Abuse, and Mental Health Administration 849
National Institute of Mental Health: St. Elizabeths Hospital 869

TUESDAY, MARCH 18, 1986

Department of Health and Human Services:
Health Care Financing Administration 949
Social Security Administration 1033
Office of Child Support Enforcement 1129

WEDNESDAY, MARCH 19, 1986

Department of Health and Human Services:
Office of Human Development Services 1153
Office of Community Services 1207
Departmental Management 1233
Policy Research 1243

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1987

TUESDAY, MARCH 4, 1986

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:30 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker, Hatfield, Andrews, Rudman, Specter, Proxmire, and Chiles.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

STATEMENT OF HON. OTIS R. BOWEN, M.D., SECRETARY

OPENING REMARKS

Senator WEICKER. The subcommittee will come to order.

Today the subcommittee will hear from the Secretary of the Department of Health and Human Services on the Department's budget request for fiscal year 1987.

HHS is responsible for ensuring the funding and delivery of services which are essential to the health and welfare of the American public and can, in fact, save the American public billions of dollars.

I have often said that the business of this subcommittee is the business of life. We fund the research which explores cures and therapies for Alzheimer's disease, cancer, and AIDS. We fund community and migrant health centers where poor women receive the kind of prenatal care which is essential for the delivery of a healthy baby. We fund community action agencies where millions of low-income people receive such basic services as food, clothing, and shelter. We fund the programs which are desperately needed by the members of our society who know nothing of the economic recovery and expansion the President so often talks about in his speeches.

It is my sincere hope that the Secretary of HHS and this subcommittee can take a look at what is really needed to adequately fund the Health and Human Services' programs, and not what is needed to

comply with some budget numbers dictated to the Department by the Office of Management and Budget.

Mr. Secretary, this is your first appearance before this subcommittee. I welcome you and invite you to proceed with your opening remarks.

I face the Secretary with mixed emotions; mixed in the sense that I think he is one of the finest appointments made by this administration to any Cabinet post. I think that even in his earliest days in office he has both shown a knowledge and a precision of expertise in addition to a compassion that I find to be rather unique in this administration.

Having said that, I think the Secretary, obviously, is a part of the Executive team and belongs to the budget of the Executive. And I am in sharp disagreement with that budget as it relates to his agency and the place of his agency in the scheme of things relative to the administration's priorities.

We will have a chance to go over that during the course of the questioning, but I feel that an important first step has been taken, both for the committee and for the American people in that, No. 1, we have somebody that is knowledgeable in the Cabinet post in the person of Dr. Bowen. And I feel that as long as there is knowledge there is always the chance for dialog and accommodation. And I look forward to that in the weeks ahead.

We are honored today with the chairman of the Appropriations Committee, who in my loneliness here in Washington, if I ever had one ally, it is the chairman. And I think when he goes, I go. It is nice to have the Senator here.

Senator HATFIELD. Thank you, Mr. Chairman. I am honored to be a part of your subcommittee.

Senator WEICKER. Fine. I do not know whether you prefer—which is the higher title, Mr. Secretary or Doctor. Or Governor. You tell me which you prefer. What do you like to be called, having had all these titles?

Secretary BOWEN. I have been called a lot of things, Senator. I have no preference. Whatever comes easier for you.

Senator WEICKER. Well, why not have it as Mr. Secretary? I think maybe that would be best.

OPENING REMARKS FROM SECRETARY BOWEN

Secretary BOWEN. Mr. Chairman and Senator Hatfield, I want to thank you for your invitation to be here today. I would like to share just a few brief remarks and request that my longer written statement be made a part of the record.

As you know, it was only last December that you honored me with confirmation as Secretary of Health and Human Services. In taking my oath of office, I was aware of the responsibilities that I was assuming, but I also was aware of the challenges.

At the State level, I served both as legislator and Governor, and at the Federal level, I have served on several advisory bodies. So I, too, am aware of the problems that we face today. I am also aware that such

problems are best solved in a spirit of mutual understanding, respect, and cooperation. It is in that spirit that I took my oath of office, and it is in that spirit that I am here today.

Our proposed departmental budget for fiscal year 1987 totals $345.6 billion. This is $12.7 billion more than our 1986 budget and it is $30 billion more than the HHS budget for 1985.

Since 1981, the Department's budget has increased by $116.8 billion. Our 1987 proposals total 34.8 percent of the Federal budget, and that means that HHS is still the largest Department in the Federal Government.

For the Department's programs considered by this subcommittee, our appropriations request for 1987 totals $82 billion.

In fashioning this budget, our priorities were: Balancing the budget by 1991 without a tax increase; containing health care costs while ensuring the quality of care; meeting our commitments to older Americans, the disabled, and the other truly less advantaged; and aiding families to enhance self-sufficiency by properly supporting the family as the vital nucleus of our society.

Included in these priorities are the Social Security cost-of-living increases. For January 1987, this increase is estimated to be 3.7 percent.

CONTROL OF HEALTH COSTS

Four years ago, double-digit inflation in health care costs threatened to price that care out of the reach of many who needed it. We have come a long way in correcting that condition, but much needs to be done if these costs are to be reduced still more.

In 1980, for example, Medicare and Medicaid outlays totaled $46 billion. And by 1985, the cost of these programs had almost doubled. And if no action is taken, the cost of these programs will triple by 1991 to $150 billion.

Our 1987 proposals include a series of major regulatory and legislative changes to hold Medicare and Medicaid outlays in check without compromising quality of care.

Our Medicare proposals are aimed at making health care affordable. They are expected to save $4.7 billion in 1987 and $54.5 billion over the next 5 years.

The principal initiatives include: Phasing hospital capital payments into the Prospective Payment System; revising graduate medical education payments; and restraining physician and other provider payments while continuing to encourage competition in health care.

Our 1987 proposals would limit Federal Medicaid payments to $23.6 billion. This would be $1 billion below the current estimate for fiscal year 1987.

Each State's share for 1987 would be limited to a reasonable and fair increase over its 1985 expenditures, plus any amount that a State might receive from a special one-time-only hardship fund. This fund is to help ease the transition. It will be made available to States encountering hardship despite bona fide cost control efforts.

For 1988 and beyond, fiscal year 1987 spending limits would be indexed to the medical care component of the Consumer Price Index.

To help States control their Medicaid spending, we will be proposing still greater program flexibility. This will enable States to target needed services to vulnerable groups to ensure the greatest payoff in preventing and resolving special health problems.

Other related measures we seek include a proposal to help States verify when recipients have third party health insurance coverage, thus avoiding the cost to Medicaid.

The administration has also proposed AFDC job search, work experience, and on-the-job training legislation that will help States reduce Medicaid costs.

CATASTROPHIC ILLNESS COVERAGE

In addition to these 1987 proposals, the President has called for an examination of how the private sector and Government can work together to address the problems of affordable insurance for those whose life savings would otherwise be threatened when catastrophic illness strikes.

We are enthusiastic about the President's charge to examine the entire question of catastrophic illness costs, including possible actions for both the private and the public sectors.

BIOMEDICAL RESEARCH

Our 1987 request for the National Institutes of Health would establish a stable level of research grants. This level would be sustainable in future years when even greater deficit reduction targets would have to be met.

Our total 1987 NIH request is $4.9 billion. This will support 18,000 research project grants and 523 research centers.

For the Alcohol, Drug Abuse, and Mental Health Administration, our 1987 request will support 1,400 research project grants.

Our 1987 request would also permit us to maintain efforts to prevent and control disease.

AIDS

As the President has emphasized, AIDS remains the highest public health priority of our Department. He has ordered a Surgeon General's report on the problem, and we have requested $213 million for AIDS research and education. Of this total, $203 million is requested for programs reviewed by this subcommittee, and $10 million is requested for the Food and Drug Administration.

The major programs of the Centers for Disease Control will be restored to their 1985 levels.

HUMAN SERVICES PROGRAMS

To further assist AFDC recipients to achieve self-sufficiency, our 1987 proposals include a work opportunity initiative. Through this new program, employable AFDC recipients would be directed into activities to help them find and keep jobs. These activities would include job search, community work experience, and on-the-job training.

Our 1987 proposals also seek an additional increase of $56 million over the revised 1986 level for the Foster Care and Adoption Assistance Programs.

We plan to restore other high-priority family-related programs to their 1985 funding levels. These include Head Start and Nutrition Programs together with services for older Americans.

Those who need our services are being served under our 1986 budget and they will continue to be served under our 1987 proposals.

SERVING CHILDREN

The Nation's children will be served as well or better than before by our proposals. Our 1987 request includes $26.7 billion for 15 key children's programs. That is nearly $400 million more than the current estimate for 1986, and it is $1.9 billion more than in 1985.

In 1987, Medicaid will serve 11.4 million children, and that is 75,000 more than in 1986, and more than 700,000 over 1985. Also in 1987, AFDC will continue to serve some 3.7 million families.

Child support enforcement outlays will be increased 10 percent. This will increase collections from absent parents by more than $249 million in 1987 and it will bring total collections to $3.3 billion.

Three child abuse and family violence programs will be consolidated into a family crisis and protective services grant to the States. It will provide States with broad authority to address this problem.

As I promised in my confirmation hearings, regulations implementing the Family Violence Program will be issued this month.

With Head Start, we propose to restore the sequestration required by Gramm-Rudman-Hollings. The nearly 450,000 Head Start children we will serve in 1987 is nearly 20 percent more than the number served in 1981.

Our efforts to improve child health care will continue. These efforts have already produced three encouraging results. A record number of children have been immunized against major childhood diseases. The infant mortality rate has been reduced to a record low of 10.4 per 1,000 live births. And life expectancy at birth has been increased to a record high of 74.6 years.

But we do not rest on these achievements, because our obligations to children are great. They are the Nation's future.

OLDER AMERICANS

So, too, are our obligations to older Americans in need of our services.

In 1987 we will serve about 5 million more meals to older Americans, both home delivered and congregate, than we did in 1985. And thanks to better management, we will do this at the same appropriations level.

While the overall national budget meets the 1987 deficit targets, funds for services under the Older Americans Act have been restored to the pre-Gramm-Rudman-Hollings level.

Under the Older Americans Act, the 1985 budget provided $669 million for nutrition and supportive services. This was reduced to $640 million for 1986, but it will be restored to the 1985 level in 1987.

FAMILIES

Of the many problems our Department confronts, Mr. Chairman, none concerns me more gravely than the endangered status of many families. While most families remain intact and resilient, others do not.

The most tragic consequence of family breakdowns is the epidemic of teenage problems. Teenage pregnancies, school dropouts, rampant drug use and the violence it spawns in our streets, homes and schools are visible signs of family breakdowns. The statistics we collect tell a vivid story.

Under a generation ago, the vast majority of all children lived in two-parent families. Twenty percent of all children born in the United States today are born out of wedlock. Often they are born to mothers who themselves are still children. In fact, 54 percent of all children born to women 19 and under are born out of wedlock.

Young boys and girls must be brought to realize that teenage parenthood is a one-way ticket to poverty. We have no choice but to address this frightening condition. It tears deeply at our national fabric.

Over the past 20 years, Government has sought to prevent much of the damage which today we see about us. I do not question the good intentions behind the Government's efforts. Intentions notwithstanding, however, we now must take a hard look at the empirical evidence of what has been wrought.

If we would change that evidence, we must first change the Nation's philosophy. If we are to fully address this problem, our schools, churches, media, and entertainment industry must assume their responsibility as well. They must do more to encourage a civilized code of conduct. No nation in history has long endured by ignoring this code.

Teaching and upholding this code is the work of the family supported by the institutions of the community. Government cannot do this job. It can only foster programs that support strong family life and sound community teamwork.

All of us who serve in Government need to take a fresh look at what Government can and cannot do to strengthen families. And we need to acknowledge that Government has not always done an effective job in support of the family. This is why President Reagan has ordered a study of our social welfare system.

We need the thinking of Congress on these questions, too. As a one-time legislator myself, I know what public debate can do to stimulate the public dialog.

Mr. Chairman, that concludes my oral statement. I will be pleased to respond to any questions. If I do not have a ready answer, I will be pleased to see that one is soon provided for the record or answered by one of my staff who is here today.

PREPARED STATEMENT

Senator WEICKER. We will place your statement in the record at this point and then go on to some questions.

[The statement follows:]

STATEMENT OF OTIS R. BOWEN

I am here today to present to you the fiscal year 1987 budget for the Department of Health and Human Services.

The priorities for health and human services we have embodied in this budget are based on two important assumptions: that spending must be tightly controlled to meet deficit reduction targets agreed upon by both the President and the Congress; and that essential benefits and services for the Nation's most vulnerable individuals and families must be maintained.

In balancing these priorities, we have been careful to meet our commitments to older Americans, the disabled, and other truly less advantaged and to support the family as the vital nucleus of our society.

For 1987, HHS will spend a total of $345.6 billion including outlays from the Social Security and Medicare trust funds, as well as from Federal funds appropriated by the Congress. For the Department's programs considered by this Subcommittee, our appropriations request for 1987 totals $82.0 billion. I will emphasize this appropriations request in the remainder of my remarks.

PUBLIC HEALTH SERVICE

For the programs of the Public Health Service (PHS) within this Subcommittee's purview, we are requesting $7.8 billion in 1987. These funds will be used to help Americans achieve improved health status by supporting biomedical research, conducting disease investigations, implementing health promotion practices, and assisting States to deliver health services.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

A total of $1,183 million is requested for activities of the Health Resources and Services Administration (HRSA). Highlights of the 1987 HRSA budget include:

o National Health Service Corps (NHSC)

The $47 million request for the NHSC will support a total field strength of 3,292 physicians and other health professionals, including 571 federally-salaried assignees in 1987. The program continues an emphasis on encouraging individuals to fulfill NHSC scholarship service obligations in health manpower shortage areas through private practice instead of as Federal employees. Since December 1983, the number of primary medical shortage areas has declined 15 percent to a level of 1,843. The number of dental shortage areas has dropped from 987 to 777, or 21 percent, during this same period.

o Maternal and Child Health and Primary Care Block Grants

The budget includes $478 million for the Maternal and Child Health and $565 million for the Primary Care block grants. We continue to support the consolidation of the Community Health Centers, Family Planning, Migrant Health and Black Lung categorical grant programs into an expanded though simplified Primary Care block grant to assist States to meet local health services priorities.

o Health Professions Education

In view of steadily increasing supplies of physicians and nurses, projected national surpluses in these occupational fields, and the improved distribution of health care practitioners to medically underserved areas, no funds are requested in 1987 for the Health Professions Education programs. These Federal subsidies were initiated 20 years ago to alleviate personnel shortages existing at that time. We have successfully accomplished this goal, and this Administration continues to believe that the time has come to phase out Federal support of these programs.

The Health Education Assistance Loan Program (HEAL) will provide $100 million of new guarantees for private loans to graduate students in health professions schools. Work is progressing to ensure the long-term solvency of the loan insurance fund. Borrowers will be required to pay an 8 percent insurance premium; lenders will share in 20 percent of the loan liability. Borrowers and lenders will also be required to purchase credit life insurance to provide for the risk of the borrower's death or disability.

o Health Planning

Federal financial support for State and local health planning activities is discontinued in 1987. The Administration has consistently advocated the elimination of Federal funding for State and local planning activities because of the program's relative ineffectiveness in controlling health care cost increases.

CENTERS FOR DISEASE CONTROL

The 1987 budget continues to emphasize health promotion and disease prevention in order to reduce the spread of disease, encourage healthy lifestyles, and help control health care costs.

For the principal prevention agency, the Centers for Disease Control (CDC), the 1987 budget request is $380 million, an increase of $13 million over 1986. Highlights of this budget request follow:

o Immunization

In 1987, $56 million is requested for the immunization program, a net decrease of $1 million below the 1986 level. Within this level, funding for State grants and technical

assistance will increase by $3 million above 1986. Through CDC leadership and provision of financial assistance to States, immunization levels of school-aged children have reached over 95 percent, and many childhood diseases, such as measles, mumps, rubella, tetanus and polio have been brought under control.

No funding is requested in 1987 for the vaccine stockpile. Through 1986, an average 16-week emergency reserve supply of all major childhood vaccines will have been accumulated in case of a stoppage in domestic production. The Administration has transmitted to Congress legislation to eliminate punitive and limit non-economic damage awards against vaccine manufacturers to help ensure that these companies can obtain liability insurance, the major factor responsible for the temporary diphtheria-tetanus pertussis vaccine shortage of a year ago.

o Preventive Health Services Block Grant

In 1987, $90 million is requested for the Preventive Health Services Block Grant to States. Funds from this block grant are provided to support State priorities in preventive health services in areas such as hypertension; emergency medical services; health risk reduction; rodent control; fluoridation; rape prevention; home health; and other comprehensive public health efforts.

NATIONAL INSTITUTES OF HEALTH

The 1987 request for the National Institutes of Health (NIH) is $4.9 billion. This budget will continue support for basic health research that will be translated into future long-term improvements in medical care and the health of the American people.

Research will continue to be pursued during this period of rapid advancements in the life sciences in such priority areas as Alzheimer's disease, molecular genetics, immune system research, diagnostic brain imaging, and development of therapeutic agents and a vaccine against AIDS. In addition, studies on low birth weight of infants and preventive strategies for many major diseases--stroke, epilepsy, and central nervous system trauma--will be enhanced.

o In 1987, $2.8 billion is requested to fund 18,000 research project grants. These research project grants will support individual research scientists who are the primary source of fundamental biomedical discoveries. Continued priority is given this key mechanism.

Increased fiscal pressures throughout the Federal budget demand that a level of stability be achieved in project grants that will not result in large fluctuations of resources for other research support mechanisms. Continuation at a policy level of 6,100 new and competing awards annually, resulting in a total of over 19,000 grants in 1987, is a level we believe is not realistically sustainable over the next several years.

In addition to a stable policy for managing resources, NIH will devote greater cost consciousness in the review and funding of project proposals.

The budget request is sufficient to provide an estimated 2 percent increase in direct costs for research project grants. Payments for the allocated overhead portion of indirect costs to research grantees will be reduced by $85 million through a cap on the administrative components.

- $198 million is requested in 1987 to support an estimated 9,258 research trainees, a reduction of 700 from the 1986 estimated level of trainees.

- $447 million is included in the request to support 523 research centers, which focus research on such important topics as hypertension, arthritis, mental retardation, and Alzheimer disease.

- All other research mechanisms, such as contracts, disease control awards, and intramural research, are maintained in 1987 at essentially the 1986 level of $1.4 billion, with the exception of the phase-out of the Biomedical Research Support Grant and the Facilities Construction Grant programs. The request includes $10 million to continue efforts to stimulate health research at minority and other smaller schools which previously have received little or no NIH funding.

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

A total of $928 million is requested in 1987, an increase of $11 million over the 1986 level, for the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) to support basic and behavioral research, training, and services to States. Included in this total is $490 million for the Alcohol, Drug Abuse and Mental Health Block Grant, $21 million more than the amount available in 1986.

- Similar to the NIH policy, priority in ADAMHA will be placed on funding 1,400 research project grants in 1987.

  Emphasis will be placed on research in the neurosciences and addressing the major problem areas of schizophrenia and depression, continuing drug abuse studies on the "reinforcing" centers of the brain, the biological mechanisms involved in the susceptibility of alcoholism, and prevention efforts.

- No funds are requested for the Clinical Training Program, since overall shortages of personnel no longer exist.

- The budget request reflects a $4.8 million reduction in indirect cost payments to colleges and universities. Overhead expenses will be reduced through a cap on the administrative components of the indirect cost rate at 20 percent of direct costs.

St. Elizabeths Hospital

In 1987, the Federal subsidy to St. Elizabeths Hospital will be $36 million, $6 million less than in 1986, reflecting the fifth year of a planned ten-year phasedown of the direct Federal subsidy for the care of District residents. The budget reflects the assumption that this decrease will be offset primarily by increased payments from the District of Columbia. In 1984, legislation (P.L. 98-621) was enacted which provides for the direct transfer of the hospital to the District on October 1, 1987. By 1992, the District will pay the full cost of care for its residents.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

The 1987 request is $405 million for programs in the Office of the Assistant Secretary for Health, an increase of $41 million over 1986. The following priority activities will be supported:

- $19 million for health services research activities to: assess the frequency of use and cost of health care; examine and improve health care delivery methods; and test the appropriateness of emerging and frequently used technologies.

- $50 million for the National Center for Health Statistics to collect, analyze and disseminate nationwide data on illness, health resources, and vital statistics. Within the request, $3 million will be used to continue preparations for the data collection phase of the next cycle of the National Health and Nutrition Examination Survey.

- $6 million is included in the budget to foster the development of disease prevention and health promotion measures, with continued emphasis on bringing to the public a greater awareness of the hazards of smoking.

- Acquired Immune Deficiency Syndrome (AIDS)

  Over the past four years, this Department has supported a major research effort on AIDS to determine its cause and control its impact in the population, to develop the means for preventing this disease, and to improve the diagnosis and treatment for AIDS. In order to highlight, plan, and coordinate the total level of resources devoted to this top public health priority, the budget consolidates expenditures for AIDS activities in the Office of the Assistant Secretary for Health. Funds are also included in the Department of Agriculture appropriations bill which contains the Food and Drug Administration's (FDA) budget request. However, operational responsibility will continue to reside in the individual agencies involved (NIH, CDC, ADAMHA, and FDA).

  The budget authorizes allocation of AIDS funds among PHS agencies as scientific breakthroughs occur and new opportunities are identified. The Assistant Secretary for Health recently appointed an AIDS coordinator to monitor projects, identify gaps in activities, and make decisions that keep these efforts on track.

Over 16,500 cases of AIDS in the U.S. have been reported to the Centers for Disease Control since 1981. Extraordinary progress has been made in a relatively short time in understanding this new and devastating disease, including identification of the causative HTLV-III virus; enhancing the protection of the blood supply for the general public and especially for hemophiliacs; initiating clinical studies of promising therapeutic drugs; and developing public health guidelines for health care workers, schools, blood collection centers and others. To continue this effort, $213 million is requested in 1987 to combat AIDS. This includes $10 million requested for FDA.

HEALTH CARE FINANCING ADMINISTRATION

The total 1987 HCFA budget request for Medicare, Medicaid and related programs includes outlays of $95 billion, an increase of $1.6 billion, or 2 percent, over the current estimate for 1986. Approximately 52 million beneficiaries will be served through the Medicare and Medicaid programs in 1987. This is a responsible budget designed to make health care more affordable.

This budget reflects the Administration's continued commitment to constrain rising Federal health care expenditures while meeting the health needs of the elderly, disabled, and poor. Although the rate of inflation in health care costs has declined during the past few years, these costs are still growing at almost twice the rate of general inflation. To moderate these cost increases, the budget request includes a number of legislative and regulatory proposals designed to slow the rate of growth in program expenditures. These proposals are expected to save the Medicare and Medicaid programs approximately $5.4 billion in 1987.

For HCFA programs which require appropriations action -- primarily Medicaid and a portion of the Medicare program -- we are requesting appropriations of $45.1 billion in 1987.

MEDICAID

Medicaid appropriations of $24.7 billion are projected for 1987. This includes $6.5 billion already provided in advance appropriations for the first quarter of 1987. In addition, $7.1 billion is requested for the first quarter of 1988. The request is based on November 1985 States' estimates and includes the impact of proposed regulatory and legislative savings of $1.4 billion.

The Administration's legislative and regulatory proposals for Medicaid are designed as incentives for States to moderate program growth and improve the efficiency of program operations. Specifically, these proposals would limit Federal expenditures for medical assistance payments to $23.6 billion in 1987, while at the same time give States greater flexibility to design and operate their medical assistance programs. A one-time, hardship pool of $300 million would be available to assist States which, despite aggressive efforts to control costs, incur expenses above their limit.

In addition, we are proposing to eliminate all special matching rates for State and local Medicaid administrative costs and to reduce matching for excessively high administrative costs. This proposal, which would save $260 million in 1987, would eliminate special subsidies which have outlived their purpose and would also provide incentives for States with high administrative costs to achieve efficiencies. Related proposals will also be advanced for the AFDC and food stamp programs, and for child support enforcement in relation to elimination of special subsidies.

PAYMENTS TO HEALTH CARE TRUST FUNDS

A total of $20.4 billion is requested for the Payments to the Health Care Trust Funds appropriation, an increase of $1.5 billion above 1986. This account reflects certain general revenue payments to Medicare, the largest being the Federal share of premiums for individuals enrolled in the Medicare Supplementary Medical Insurance (SMI) program (Medicare Part B). The growth in the Federal payment for the Part B program is primarily a result of rising program costs and increased utilization of physician and outpatient services. The appropriation request represents approximately 75 percent of total Part B program costs. Enactment of FY 1987 Medicare legislative proposals would reduce Payments to Health Care Trust Funds by a total of $1.3 billion.

PROGRAM MANAGEMENT

The 1987 budget request includes $85 million in appropriations and $1,164 million in trust fund transfer authority to administer the Medicare and Medicaid programs. Highlights of the program management appropriation include:

- Medicare Contractors

  A total of $957 million is requested, an increase of $37 million above 1986. In addition, we are requesting a $50 million contingency fund, $35 million more than 1986, for unanticipated workloads. Approximately 76 percent of the budget request for the Medicare Contractors, or $728 million, is allocated to claims-processing services. The remainder of the request will be used largely to assess the quality and appropriateness of health services provided to beneficiaries.

- State Survey and Certification

  The $57 million request, an increase of $8 million above 1986, supports survey coverage of approximately two-thirds of the facilities participating in Medicare. This level will provide annual inspections of all skilled nursing facilities and reflects the Department's continuing commitment to protect the health and safety of Medicare beneficiaries.

- Administrative Costs

  A total of $215 million is requested for Federal administrative costs, $9 million more than in 1986. The

1987 request will support 3,757 FTEs, a reduction of 143 FTEs from 1986, accomplished through attrition and streamlining administrative processes and requirements.

o Research

A program level of $19 million is requested for the research demonstrations, and evaluation programs in 1987. Priorities will include refinement of the hospital prospective payment system, testing feasibility of capitated systems, and development and testing of alternative payment systems for skilled nursing facilities.

SOCIAL SECURITY ADMINISTRATION

The fiscal year 1987 budget for the Social Security Administration's (SSA) income security programs for the aged, disabled and poor totals $234.7 billion in outlays financed through both trust funds and general fund appropriations. These programs, which constitute about 68 percent of HHS budget outlays, will provide benefits to over 51 million people in 1986.

For programs subject to appropriations, we are requesting $27.5 billion for 1987, including previously appropriated advances of $4.8 billion. Advances of $5.3 billion for the first quarter of 1988 are also requested. The appropriations request by program is as follows:

SUPPLEMENTAL SECURITY INCOME (SSI)

The 1987 appropriations request for the Supplemental Security Income program is $10.5 billion, including a previously appropriated advance of $2.3 billion. For the first quarter of FY 1988, an advance appropriation of $2.8 billion is requested. Federal benefit payments under this program will provide assistance to an average of 3.9 million recipients each month.

The 1987 budget request supports the Administration's commitment to a cost-of-living increase of 3.7 percent payable in January 1987 and a projected increase in the blind and disabled population.

AID TO FAMILIES WITH DEPENDENT CHILDREN (AFDC)

Total appropriations of $8.2 billion have been requested for Assistance Payments for 1987, of which $2.2 billion has already been provided as an advance appropriation. Also, $2.3 billion is requested in advance for the first quarter of 1988. These funds will provide assistance to an average of 3.7 million families each month.

The request includes several legislative proposals, three of which continue proposals previously made in this program. They are intended to ensure that assistance is provided only to those who are in need and who are not in a position to provide for themselves, and that strong work requirements exist for all

able-bodied applicants and recipients. In 1987, these legislative proposals are estimated to result in net AFDC savings of $237 million.

REFUGEE AND ENTRANT ASSISTANCE PROGRAM

In 1987, the budget request for Refugee and Entrant Assistance programs totals $374 million in budget authority. This represents an increase of $52 million above the level of funds available in 1986, but includes $79 million of costs associated with new legislation previously funded from other accounts.

Legislation will be advanced to reduce welfare dependency among refugees, which is currently too high. The proposal would finance all refugee cash and medical assistance through this account under program rules more tailored to refugees' circumstances. This will give States more flexibility to provide job skills, work experience, and other employment services than is possible under normal AFDC rules. The proposal would not affect the availability or level of benefits, only the financing arrangements. This change would cause a $109 million increase in funding for Refugee and Entrant Assistance that would be offset entirely by reductions in the AFDC and Medicaid programs. Another component of the proposed legislation would, for 18 months, give States full payment for aid to needy refugees. After the initial 18 months, refugees could receive aid on the same basis as other residents. This change saves $30 million, compared to the cost of the current 36-month period of full repayment to the States, for a net change of $79 million due to proposed legislation.

In view of the lower and more stable refugee arrival rates of recent years, no funds are requested for targeted assistance or education assistance.

OTHER SSA PROGRAMS

We are requesting $2.1 billion for the Low Income Home Energy Assistance program, $1.0 billion for Special Benefits for Disabled Coal Miners, and $0.5 billion for Payments to Social Security Trust Funds, primarily for taxes due on certain military service deemed wages.

LIMITATION ON ADMINISTRATIVE EXPENSES

The Limitation on Administrative Expenses provides resources for SSA to administer the Old Age, Survivors, and Disability Insurance programs, certain health insurance functions, and the Supplemental Security Income program.

For 1987, we are requesting authority to spend $4.0 billion, an increase of $163 million compared to 1986. The request includes an increase in the contingency reserve from $139 million to $160 million. This will provide the flexibility to deal with the many uncertainties in 1987 associated with implementation of the disability reform legislation and managing the impact of automation on SSA's employees and organization.

SSA will continue progress on its Systems Modernization Plan which is replacing SSA's outdated system of hardware, software, and storage capacity with one that is modern, efficient and reliable. To date, software and systems upgrades have reduced processing times and error rates, and improved SSA's service to the public. Productivity and service improvements are expected to continue at an even greater pace over the next few years.

OFFICE OF CHILD SUPPORT ENFORCEMENT

Vigorous implementation of changes made by the Child Support Enforcement Amendments of 1984 will continue to be a major priority in 1987. Total 1987 appropriations requested for the Office of Child Support Enforcement are $729 million, including an advance appropriation of $171 million. This represents an increase of $143 million over 1986. We are also requesting an advance appropriation for the first quarter of 1988 of $187 million. We estimate that child support collections will have more than doubled since 1980, from almost $1.5 billion to almost $3.3 billion in 1987, an increase of 8 percent or $249 million compared to 1986.

OFFICE OF HUMAN DEVELOPMENT SERVICES AND OFFICE OF COMMUNITY SERVICES

We are requesting $5.5 billion in appropriations for programs administered by these offices in 1987.

The budget continues the policies of this Administration to support social services and related programs which promote self-sufficiency among program recipients, while focusing Federal resources on the most effective and efficient programs. In sum, the 1987 budget will increase funding for Foster Care and Adoption Assistance; maintain most other service programs at current levels; reduce funds in selected research, training, and discretionary areas; and eliminate funding for the Community Services Block Grant and the Work Incentives programs.

BLOCK GRANTS

The 1987 budget request for the Social Services Block Grant is at the full authorization level of $2.7 billion. No funding is requested for the Community Services Block Grant. Instead, the Department proposes that States use other sources of funding, including the Social Services Block Grant, to support those Community Services activities which are of the highest priority and most effective.

HEAD START

A total of $1,075 million is requested for the Head Start program, an increase of $35 million over 1986. This program provides comprehensive support services and early childhood development for poor and handicapped children up to age 5. This level will support services to over 448,250 children, the same number as in 1986. Of the total enrollment, at least 10 percent will be handicapped.

FAMILY CRISIS AND PROTECTIVE SERVICES

The 1987 budget contains $30.5 million for a consolidated Family Crisis and Protective Services Grant Program. By combining three existing programs which address child abuse and family violence, this new grant will give States greater latitude in preventing, identifying, and treating all forms of abuse.

AGING PROGRAM

The 1987 budget includes a total of $689 million for Aging programs.

Within this total, $669 million is requested for activities under Title III of the Older Americans Act, the same level as provided in 1985 and an increase of $29 million over 1986. These activities include supportive services and centers, the nutrition programs of congregate and home-delivered meals, and State agency administration.

The budget request also provides $7.5 million for grants to Indian Tribes, restoring the amount sequestered by the Balanced Budget Act of 1986. This level will provide approximately 135 grants, serving over 24,000 older Indians.

DEVELOPMENTAL DISABILITIES

A total of $75 million is requested for activities to develop and expand services for persons with developmental disabilities, the same level provided in 1986. Past employment efforts have been quite successful: in 1985 the Administration on Developmental Disabilities placed 58,000 persons with developmental disabilities in competitive employment. The 1987 level of funding will provide continued support for the Administration's effort to increase private sector employment opportunities for developmentally disabled individuals.

FAMILY SOCIAL SERVICES

The 1987 budget requests a total of $818 million for programs to keep families together or to support other appropriate living arrangements when reunification of children and families is not possible. The amount requested is an increase of $58 million over the program level for 1986. The request continues support for legislation introduced as part of the 1986 budget which would: remove barriers to Medicaid coverage for children with special needs adopted under the Adoption Assistance program; modify requirements for Foster Care financing; and create incentives for States to reduce the duration of children's stays in Foster Care services.

The $818 million requested includes $544 million for Foster Care, $60 million for Adoption Assistance, $200 million for Child Welfare Services, $4 million for Child Welfare Training, and a total of $10 million for Child Welfare Research and Demonstrations, Adoption Opportunities and Social Services Research activities.

WORK INCENTIVES

In 1987, no funds are requested for the Work Incentives (WIN) program because, as studies by the General Accounting Office and others have demonstrated, this program has not been effective in providing training or work experience to the AFDC recipients who needed it the most. Instead, the budget continues to advocate legislation introduced last year which requires job search and work activities for AFDC recipients in all States, while giving States flexibility in the design of their specific work programs. These proposals build on legislation of the past five years which have given States powerful alternatives to regular WIN programs: community work experience, WIN demos, and grant diversion. Under our proposal, States would have the flexibility to maintain or further develop innovative work alternatives now funded with WIN monies, such as those in place in California and Massachusetts, or to go beyond these programs to develop other approaches suited to the needs of their AFDC recipients.

DEPARTMENTAL MANAGEMENT

The 1987 budget also includes a $230 million program level for activities under the Departmental Management appropriation. Departmental Management activities include the Office of the Secretary, the Office of Inspector General, the Office for Civil Rights and the Policy Research program.

For 1987, the budget proposes further staffing reductions in the Office of the Secretary (General Departmental Management) through management improvements. An employment decrease of 84 full-time equivalent (FTE) staff will be met through attrition under closely managed hiring and employment practices.

In our Office of the Inspector General, we will target audit and investigative efforts on the large dollar programs which provide the greatest opportunity for fraud, waste, and abuse savings and recoveries. For 1987, we expect total recoveries, restitutions, fines and cost avoidances to continue at the levels achieved during the past few years.

This budget also carries out our obligations to assure civil rights compliance among the Department's federally-assisted programs and services. The $19.3 million program level request will allow the Office for Civil Rights to continue its comprehensive compliance program which includes voluntary compliance and outreach, reviews of recipient compliance, and prompt investigation of complaints of discrimination.

The $5 million requested for Policy Research in 1987 will continue funding available to the Department under its only flexible research authority for work on issues of national policy significance in the health, income maintenance, and social services fields.

PROPOSED FISCAL YEAR 1986 RESCISSIONS

The 1987 budget proposes to rescind $724 million in 1986 budget authority for programs reviewed by this Subcommittee. In general, these proposals seek early elimination of programs previously identified as unnecessary or ineffective or initiate reductions in the second half of 1986 as a means of moderating reductions that would otherwise be required in 1987 under the President's Budget. Major proposals include:

- o $182 million for elimination of funding for the Community Services Block Grant in the second half of 1986.

- o $164 million for termination of support for Health Professions Education and Health Planning.

- o $102 million in funding for the National Institutes of Health and the Alcohol, Drug Abuse and Mental Health Administration to provide a necessary transition to a stable level of 19,400 project grants in 1987.

- o $88 million for Refugee and Entrant Assistance to reduce excessive spending on activities that were helpful in 1980 when the influx of refugees was very large and immediate but which are no longer necessary now that the flow of refugees is much smaller and relatively stable.

- o $46 million for phase-out of the Work Incentives program in 1986 as a prelude to legislation for a new Work Opportunities program under AFDC in 1987.

EFFECT OF THE BALANCED BUDGET ACT ON HHS PROGRAMS IN 1986

FY 1986 budget estimates include the effect of the mandatory sequestering provisions of the Balanced Budget Act.

These provisions require a total reduction in Federal outlays of $11.7 billion, of which $5.85 billion is to come from non-defense spending including selected HHS programs. Because more than 70 percent of HHS outlays are totally exempt from reductions and other programs are subject to special rules, sequestering of HHS budgetary resources in 1986 results in outlay reductions of $791 billion for programs under the jurisdiction of this Subcommittee as follows:

- o $47 million from other programs subject to special rules such as Child Support Enforcement, Community and Migrant Health Centers, Foster Care, and Adoption Assistance.

- o $744 million from a 4.3 percent across-the-board reduction for all programs not otherwise subject to special treatment.

- o No reductions are included for benefit or vendor payments from the exempt entitlement programs: Supplemental Security Income, Aid to Families with

Dependent Children, and Medicaid. However, the spending authority associated with the Federal cost of administering these programs is subject to sequestering of 4.3 percent.

Mr. Chairman, in partnership with the Congress, this Administration has restored the faith of the American people in the future and in our ability to solve the major issues of the day. The policies of the last five years have succeeded in ushering in a period of strong economic growth that has benefitted all Americans. Together, we have preserved the Social Security Trust Funds from insolvency so that young and elderly Americans alike can now look with confidence to their retirement years. Health care costs have also been restrained through the introduction of a prospective payment system, though more needs to be done if we are to have quality health care at an affordable price.

We can be proud of these achievements, but we must now face the very difficult task of reducing Federal spending and the Federal deficit in order to preserve the gains we have already made. I look forward to working with the Committee to meet this goal.

That concludes my remarks, Mr. Chairman, and I would be happy to answer your questions at this time.

Biography of Otis R. Bowen

Otis R. Bowen, M.D., was sworn in as secretary of health and human services Dec. 13, 1985, by U.S. District Court Judge Sarah Evans Barker. He was nominated by President Reagan Nov. 7, 1985, and confirmed by the Senate Dec. 12, 1985.

As head of the Department of Health and Human Services, Dr. Bowen oversees the federal agency responsible for the major health, welfare, food and drug safety, medical research and income security programs serving the American people.

A former two-term governor and member of the state House of Representatives in Indiana, Dr. Bowen came to HHS from the Indiana University School of Medicine in Indianapolis where he was serving as Lester D. Bibler professor of family medicine and director of undergraduate family practice education.

Dr. Bowen was born in Richland Center, Ind., Feb. 26, 1918. He received a bachelor's degree in chemistry from Indiana University in Bloomington in 1939 and his M.D. degree from the Indiana University School of Medicine in 1942. He interned at Memorial Hospital in South Bend, Ind., 1942-1943, and served in the Pacific Theatre during World War II as a member of the U.S. Army Medical Corps, 1943-1946.

Dr. Bowen was coroner in Marshall County, Ind., from 1952 to 1956. He served as a Republican member of the House of Representatives in Indiana in 1957, 1958 and 1961-1972, serving as Minority Leader, 1965-1966, and as Speaker for three terms, 1967-1972. He was governor of Indiana from 1973-1981.

He has served on a number of federal advisory bodies, including: chairman, Advisory Council on Social Security, 1982-1984; member, Presidential Advisory Committee on Federalism, 1981-1983; member of the Advisory Commission on Intergovernmental Relations, 1977-1979; President's Committee on Science and Technology, 1976-1977; and member of the Commission on Federal Paperwork, 1975-1977.

Other bodies he has served on include the Two Year Study on Nursing and Nursing Education, Institute of Medicine, National Academy of Sciences, 1981-1983; and the Education Commission of the States, 1973-1983 (chairman, 1978-1979).

Medical organizations in which Bowen holds memberships are the Marshall County Medical Society, Marion County Medical Society, Indiana State Medical Association, 13th District Medical Society, Indiana Academy of Family Physicians and the American Academy of Family Physicians.

Bowen has received honorary doctorates from 19 institutions of higher education including Indiana University, Indiana State University, Ball State University, University of Notre Dame and Purdue University.

Honors and awards received by Bowen include the merit award of the Indiana Public Health Association, its highest honor bestowed on an individual, for outstanding achievement in health; and the AMA's first Benjamin Rush Award for outstanding contribution by a physician in citizenship and public service.

He is a member of the Kiwanis Club, Phi Beta Pi, Alpha Omega Alpha, Delta Chi and Family Practice Club, IAFP.

Dr. Bowen has written extensively on health, welfare and educational matters.

He is married and has four children. He is residing in Alexandria, Va.

WORKING RELATIONSHIP WITH SUBCOMMITTEE

Senator WEICKER. Senator Hatfield.

Senator HATFIELD. Mr. Chairman, thank you very much.

I want to say to the Secretary that, if you have not discovered already, that you are going to have a very close working relationship with this subcommittee, and particularly its chairman, Senator Weicker, whose physical immensity is equaled by the level of compassion and heart that projects him into the center of these issues that you deal with. He is a great ally. I look forward to a whole new alliance between the two entities here, our committee and your Department, to solve some of those problems that you have touched on.

I have two questions I would like to put to you at this time.

Mr. Secretary, I know that you cannot be held responsible for the actions of your predecessors, but let me just give you a particular problem that I have had.

GOOD SAMARITAN—LINFIELD SCHOOL OF NURSING

Twenty-two months ago I contacted the Secretary's office in regard to a reimbursement dispute that had developed between HCFA and the Good Samaritan—Linfield School of Nursing in Oregon. Nine months elapsed before I received a response from the Secretary which even began to address the issues originally raised and to this day, in fact, I have still not received a final response from your office. That is 22 months from our first contacts on the matter.

Needless to say, I am appalled by the continuing delay displayed by HHS and I am anxious to know if you intend to ensure that this kind of unresponsiveness is not continued.

Now, the issue is simply that since the beginning of the Medicare Program, regulations have provided for payments of costs associated with approved medical education programs.

As providers, such as Good Samaritan Hospital, they have been reimbursed for nursing education costs that they have incurred during their

own program; now, in order to increase the standard of educational excellence, they entered into a relationship with Linfield College to upgrade a nursing diploma to a baccalaureate degree. And this was designed only to improve the quality already in their nursing program. But as a consequence, the Department decided to penalize the hospital for doing this, and refused to provide for continuing Medicare reimbursement as they had provided under the strictly nursing diploma curriculum.

I am hopeful that in the bowels of your Department you can find my original letter addressing this issue. If not, I will be happy to supply you with a copy of it, and hopefully we can resolve this particular issue. It is only one case, but it could very well affect other States as well.

Mr. Secretary, my second question. On page 6.

NIH RESEARCH GRANTS

You talk about the 18,000 research project grants. Mr. Secretary, last year Senator Weicker and I and others negotiated in the late night hours with Mr. Stockman and the OMB to bring the new and continuing grants level to 6,100. That was an agreement made between the participants in that session.

As I extrapolate the figure for this year's budget, it will be reduced to 5,104. A grant reduction by 1,000.

Now, I suppose we really could argue the question of 5,100 versus 6,100. Well, Mr. Secretary, let me get this into some kind of context. There are 4,200 scientists at present involved in cancer research. There are 5,000 scientists and engineers who are involved in the SDI project research.

In fiscal year 1987, if the Congress approves the President's budget, the cancer research will remain fairly level, perhaps lose 100.

Mr. Secretary, the scientists and engineers that will be requested for employment in the Strategic Defense Initiative [SDI] will escalate to 18,600.

POOL OF SCIENTISTS

Now, my question is that since 4 out of 5 research dollars from the Federal Government goes to the military and since there is a limited pool of person power available for research in this country, I would like to know if you have any information that you can provide us indicating what kind of a secondary educational pool or baccalaureate degree pool or postbaccalaureate degree pool, what the trends are in providing for a greater increasing demand for scientists and researchers.

I have a great concern that if we do not plan for that kind of a pool down the road regardless of how much this committee may appropriate, how many grants we may have available, we may not have capable individuals in a position to apply or receive such grants.

As the competition for military research begins to absorb and suck up the available person power pool, the medical research pool is either diminishing, limited, or static. I would like to know what those facts

are, because I think it is a rather fruitless argument we get into, whether we want to establish a funding level for 5,100 new and continuing grants, 6,100 or 18,000, when one project of the military will demand more than the total number of grants in NIH.

Secretary BOWEN. I will try to answer your first question first.

QUICK RESPONSE TO CONGRESS

I am not aware of the specific problem you addressed. I will look into it; 22 months is a long time for expecting an answer. I want to assure the chairman and the rest of the members of the committee that one of my priorities is to try to get the turnaround on questions—especially those from Members of the Congress—within a very short period of time.

We have a new Executive Secretary and a new Chief of Staff who have already been instructed that this is very important. We will look into this issue, and I will try to get you an answer concerning your specific problem.

REDUCTION IN RESEARCH PROJECTS

The next issue concerns the reduction in the number of research project grants. The reduction is due to the Gramm-Rudman-Hollings reductions. This country owes its research standing in the world to the very fact that we have devoted a great amount of effort and funding to research and development; it is very important to maintain that position.

I can only state that we have tried to establish a stable level of research grants with the magic figure being 18,000 grants. We will support 523 research centers. This is 11 centers under what we had previously supported.

There will be a minimum of 5,140 new and competing grants, and 12,860 continuation grants. The 5,140 is below the level reached in 1985, and the reason for that is simply the cost. Every additional 100 projects, or grants, generates 3 years' costs of $50 million. Thus, the increase to 6,500 projects added $750 million over the previous 3 years. It is not our desire to reduce the research level, but we did have to consider the cost.

The average project grant is $156,700 and we have 50,000 scientists involved in all this. We will try to make up for some of the reductions with quality.

For example, we have three Nobel Prize winners on the staff at the present time. I was suprised to find we have 63 Nobel Prize winners with research projects. So I think our quality of research should be extremely high.

I have a lot more information that I will be glad to give you, if you so desire.

Senator HATFIELD. I was just basically concerned about the growing competition for those scientific people.

Secretary BOWEN. I might add that there is emphasis in awarding grants to make sure that a fair proportion is given to young scientists who appear to have great prospects and also a greater amount is given to those who have a productive record.

RESEARCH WORK FORCE

Senator HATFIELD. Mr. Secretary, we are told that there is a diminishing number of young people coming into the profession, particularly the medical research end of it, who are interested in going into research. And, again, my point is simply, what is happening to that pool of people who would be available for such grants in light of the competition for those same basic physics and chemistry and other such majors out of our colleges, out of our high schools, for competing research programs such as SDI, and I use it only as an example. What is happening to that pool?

I am told by medical people that there are fewer and fewer people graduating from medical schools who are interested in research. They have to get out there and try to recover their investment, and get into the practice.

Secretary BOWEN. I am not convinced that that is the case for the next few years, simply because we do have an increased number of medical school graduates. We are now up to almost 500,000 and we have the numbers problem essentially solved, but the distribution problem is still there.

I think as the competition for places in which to practice gets keener, you are going to find more and more who will be interested in going into the scientific field. But that is something that we will look into.

Senator HATFIELD. Could you please?

Secretary BOWEN. Yes; we will. I think it is important we do.

Senator HATFIELD. Thank you, Mr. Chairman.

Senator WEICKER. Thank you very much, Mr. Chairman.

ENTITLEMENT/DISCRETIONARY PROGRAMS

Mr. Secretary, while the overall HHS budget has grown, most of the increases have been in entitlement programs, and those programs are mandated by law and neither you nor the subcommittee has discretion over entitlement spending. So I think it is important to note that while the overall HHS budget is up, discretionary spending is cut $1.6 billion in the 1986 appropriations. And that is a cut of 12 percent in discretionary spending.

Would you like to comment on that?

Secretary BOWEN. I know that we do have major reductions in discretionary programs, but once again the demand through the Gramm-Rudman-Hollings Deficit Reduction Act was such that we had little choice. At a time when discretionary programs across the Federal Government are being eliminated or drastically reduced to meet the deficit reduction targets, I think we have been able to maintain the current spending levels for discretionary programs that provide services directly to individuals and families.

The 1987 request for these programs excluding the CSBG will actually increase by $215 million compared to the 1986 level. And the Department's principal service programs are being maintained at current funding levels. Those would be: the Low-Income Home Energy Assistance Program; Head Start; aging; nutrition and supporting services; Maternal and Child Health; the ADAMH block grant; child welfare services; the prevention block grant; State grants for child abuse and family violence; and the adult mentally disabled.

The major exception to this is the community services block grants which we have asked——

GRAMM-RUDMAN-HOLLINGS PRIORITIES

Senator WEICKER. The first thing I would like to point out, occasionally you and I will disagree, is a matter of both rhetoric and also underlying principle.

There is nothing mandated by Gramm-Rudman-Hollings on this budget we are discussing. You know, we are not discussing any 1986 cuts. We are discussing fiscal 1987. Nothing has been mandated. I even see the author here. Has anything been mandated by——

Senator Rudman. I have been sitting here awfully quietly but I will wait my turn.

Senator WEICKER. All right. I do not think anything has been mandated at all. It is entirely, as a matter of fact, a matter now of choices and priorities between the Executive and the Congress.

My good friend, Senator Rudman, knows I voted against his measure. I am critical of it not only in a constitutional but from a substantive standpoint.

For God's sake, let us not lay any more at his door than is already at his door.

Senator RUDMAN. We are enjoying it all, Senator Weicker.

Senator WEICKER. So I want to make that point, because I think it is terribly important to everything that flows in terms of the discussions that the administration has with the subcommittee. You are free to recommend anything that you want to, and so are we. And if indeed we fall short then maybe further action has to take place. But right now we have all of our options open to us.

And I notice that you refer in your statement to restoring to 1985 levels, spending in various programs. I would like to know whether or not the administration's request for defense spending was restored to 1985 levels. And I think you and I are well aware as to what happened. The automatic cut took place in the 1986 fiscal year and that was automatically restored in the 1987 request plus an addition. Why should we not be doing that? Why should we not restore that automatic 1986 cut, which admittedly had to take place? Why should we not restore that and move on from there? Why are we boasting about the fact that we are restoring 1985 levels? I do not understand that.

Senator HATFIELD. Well, Mr. Chairman, if I could interrupt at that point, because we are keeping two sets of books. Only the nonmilitary spending creates a deficit. Military spending does not add to the deficit.

Senator WEICKER. OK. I see.

Senator HATFIELD. Do you understand that now, Senator Weicker?

Senator WEICKER. I detect a slight note of sarcasm there in the chairman's voice. But if indeed there is no intent to be sarcastic, then I might suggest to the chairman that he has been going down to the White House too often.

I point this out because I do want us to understand where the level of the dialog is going to take place here and to my way of thinking it should take place as it relates to fiscal year 1987 and what needs to be done.

Secretary BOWEN. I apologize. I was wrong on that.

Senator WEICKER. Now, let me ask my principal question because it really relates to the whole, and then we will start the questioning going on a 5-minute cycle.

I will tell you what my concern is. My concern—let us assume that fact that we are all just acting on the basis of fiscal responsibility. I will accord to no one in the room any warmth of heart or compassion or anything. Strictly on a fiscal basis, strictly on a fiscal basis.

EFFECT IN OUT YEARS

My concern is that many of the cuts that are being proposed by the administration, that is, community health centers, NIH research, immunization, health professions training, those four right there, those proposed cuts from a fiscal point of view will be devastated in the out years—in effect what you are doing by either a level funding or a cut is to incur huge out-year obligations.

I would like your comment on that.

Secretary BOWEN. I would prefer, if you have no objection, to having one of my staff help out on that, Mr. John O'Shaughnessy.

Mr. O'SHAUGHNESSY. In putting the budget together, the Department tried to assure that we had a good policy basis for reductions. If the point of the question is that by reducing expenditures, we are harming the population, that we will have to fund through Medicaid or other programs, even greater liabilities than we might otherwise have—that would in fact be true. The reductions could result in greater liabilities for the Federal budget overall.

If you look at the major reductions, out of the $1.2 billion reductions you mentioned, many of the cuts result from certain rescissions, such as that proposed for the community services block grant, a program the Department feels is in a large part duplicative; the Work Incentive Program, for which we would substitute the Work Opportunities Program; and the Health Professions Education Program, where the Department has argued for a number of years that there are sufficient health professionals in the market place. That is the kind of thinking that went into calculating the reductions that have been proposed, not a short-term view that by cutting dollars we are going to get the deficit down this particular year.

I know for a fact that that is not at all what the Secretary would have been willing to do at any point in this budget process.

HEALTH REDUCTIONS

Senator WEICKER. An example, community health centers that you people propose to block grant and I think we can pretty well get rid of that thought, and do not spend too much time on it because you have a lot of other things to go ahead and do. It certainly is not going to clear this committee.

But the community health centers, I am sure, Dr. Bowen, that I do not have to tell you this. You certainly know the difference in cost between a healthy baby and a low birth-weight baby. It is staggering just in the difference. And yet we are cutting back on our community health centers. That is the first line of prenatal care.

The NIH research—I will just pick one off the top of my head. Alzheimer's, $25 billion for the economic cost of Alzheimer's. Why would we want to cut back—never mind? I can go to cancer and all the rest. They all fall in the same category.

The health professions education training. I mean, to me again this is just a key to our future costs.

I put in, for example, I will give you a small one. How much did we put in for the geriatric centers? Five million dollars. At the present time, out of 122—am I correct on 122 medical schools? Is that what we have, recognized medical schools in the United States? Two give courses in geriatric medicine. When we know that by 2010, we are going to jump from an average age of 75 to 85, with everything that attends to that. So I put in $5 million to start to encourage the medical schools to give courses in geriatric training, and I think that is wise money, in a sense that the money is going to save, to have a bunch of people out there prepared to deal with this problem.

It was cut by the administration. Totally. Down to zero. Now, you tell me, since you talk about the empiric evidence relative to families, I would say that we have those facts in hand now exactly as to what the aging population is going to be at a given point in time. And yet we are not going to be prepared for it. Not going to be prepared for it.

This is my concern. I do not want to overly dwell on this question, but it is going to come back in some form or another vis-a-vis your budget from this chairman. Because what I will not do is try to achieve something for the year 1987 that I know is going to cost billions of dollars in the nineties. I will not do it. I might not be here. I might not be here. The President is not going to be here. But the fact is I think we have a responsibility, at least on the Appropriations Committee not to engage in that kind of sleight of hand.

Senator Chiles.

Senator CHILES. Thank you, Mr. Chairman.

WELCOME FROM SENATOR CHILES

Mr. Secretary, I want to join the chairman and other members in welcoming you to the subcommittee. It is good to see someone of your caliber and with your credentials at the helm of the Department of Health and Human Services.

I particularly would like to commend you on the leadership that you are taking on pressing national issues such as the need for adequate catastrophic coverage for the elderly.

Our No. 1 problem that we have been talking about today is our deficit and it is on our minds and certainly is going to be all year long. But as we look at that immediate goal of how we reduce the deficit, and obviously, as the chairman has said, we have to try to keep that long-range goal in mind at the same time. We know we are in fierce competition with the other industrialized nations for world markets and productivity. And we know that if we are going to stay on top economically in defense and everything else, you have to have a healthy Nation. That is just going to be a prime requisite for trying to do that.

INFANT MORTALITY

And, of course, one of those key measures of our health is our children and our infant mortality rate. In 1985, the state of the World's Children report ranks the United States as 16th. We actually decreased that from 17th last year. And the good news is that the children's defense fund projects that we have a shot at the Surgeon General's goal of 9 deaths per 1,000 live births in 1990. However, there are still such wide gaps between the 9.7 infant mortality rate for whites and the 19.2 per 1,000 for blacks, and the 16.8 for other nonwhites. And there are certainly wide geographical differences.

The District of Columbia and our 11 southern States all rank very, very low and well below what we see our Nation's average being.

So it does not look like we are going to come anywhere near meeting the Surgeon General's goals for nonwhites or in the South.

In your role as Secretary of HHS, what is your strategy for making progress in infant mortality, particularly for blacks and those regions in the country that have the furthest to go?

Secretary BOWEN. I do not think that we can apologize for the progress that has been made because it has been terrific. In 1960, for example, the death rate was 26 per 1,000 and now, just 25 years later, it is down to 10.4. But that still does not mean that we should rest on our laurels. And that is for the average.

The very serious part is, as you mentioned, the difference between the ratio of black to white deaths.

We have recently completed the study on minority health. This is a blueprint for study, now that we know the actual facts. We need to determine the actual causes, one of which is the difference in the newborn weights.

One means by which we can attack the problem is a system of tracking the birth and death certificates. That has never been done. I think

that would give us a lot of demographic information to help us come up with some answers.

PRENATAL CARE

Prenatal care, of course, has to be stressed and in every child health program, and we are stressing that. There is a difference in the percentage receiving prenatal care. Eighty percent of white women get prenatal care; only 61 percent of black women receive this care. We need to have an outreach program to make sure that they get early prenatal care.

We have to determine the causes for low birth weights. Certainly the smoking in pregnancy has been tagged as one of the causes. Drinking during pregnancy is one of the things that causes deformities and mental retardation of children. In fact, it is one of the biggest causes of retardation.

We have statistics indicating that 26 percent of all pregnant women smoke, but 40 percent of the teenagers smoke. That is one of our big problems. Sixty-one percent do not drink at all during pregnancy, but 36 percent have one or two drinks a day during pregnancy. These bits of information we use to educate and stimulate the physicians who care for pregnant women to stress this in their prenatal care.

I can reassure you that this is one of my top areas of interest, and we are going to do everything we can. If you have some special ideas, we will listen.

HIGH-RISK GROUPS

Senator CHILES. Thank you, sir. I do and I am concerned. A recent University of North Carolina study indicates that perhaps we are not making the progress that we think we are, that we are going backwards in some ways in reducing infant mortality among the high-risk groups.

They show that in 1983 the incidence of low birth weight increased for both blacks and whites, and the annual rate of improvement would have to be around 300 percent to meet the Surgeon General's goal of reducing low birth weight to about 5 per 1,000 live births. The gap between the white and black rates is getting wider. In 1983, the gap was the widest in 40 years. Death rates are rising for babies who survive the first month of life. Data indicate that the postneonatal deaths are projected to rise again in 1984. That would be the worst situation that we faced in 20 years, and these deaths are the ones most closely associated with preventable factors due to poverty.

The percentage of women getting no prenatal care or delayed care in the third trimester is on the increase for the third year in a row. To achieve the Surgeon General's goal of 90 percent of women getting the early prenatal care in the first trimester, our rate of progress would have to be 650 percent each year through 1990.

Finally, our rate of decline in infant mortality has slowed to about 3 percent per year between 1981 and 1983.

In light of these factors, do you think we are going to meet the Surgeon General's targets for reducing risk factors in the population at highest risk and how are we going to do it?

Secretary BOWEN. Reaching this goal will require some extra special efforts. The efforts will have to focus on education about the need for adequate prenatal care, reduction in smoking, reduction in alcohol consumption, and especially adequate nutrition.

MINORITY HEALTH

We have this year created a new office on minority health and have appointed a physician, Dr. Herbert Nickens. His sole job is to try to find ways to improve the health of minorities, from infants to old age. There is a $3 million appropriation which was a new appropriation in 1986 for that office. We will be looking to Dr. Nickens for some innovative ideas.

Senator CHILES. This is my last question then.

I would like to know if you find the administration's request for programs that serve pregnant women and children adequate to make the kind of gains that we need to make in infant mortality. I know, for instance, the budget request for maternal and child health would not even bring the program back to the original 1986 appropriation. Yet this is the funding source for Florida's preterm birth prevention program that contributed to the biggest annual drop in infant deaths my State has ever seen.

Secretary BOWEN. We will make every effort we possibly can to see that there is no reduction in efforts to promote healthy newborn infants and to see that their survival rate improves each year. I am aware of the study in which Mr. Mott stated that between 31 days or 30 days in 1 year that there has been an increase. There is some question as to whether or not that is totally accurate. I have heard both sides of it. But certainly it is a study that we cannot ignore, and we are investigating it.

Senator CHILES. Mr. Chairman, I have some other questions I will submit for the record.

Senator WEICKER. Thank you very much, Senator.

There will be others. Senator Specter has also introduced questions for response in the record. There are quite a few of those and I would appreciate if those responses would take place within the next several weeks.

Senator Andrews.

Senator ANDREWS. Mr. Secretary, it is good to have you on board. I remember a pleasant time some years ago when you and I talked at the Tidewater conference. At that point in time I was very impressed with your record in Indiana and we look forward to the great things we are sure you will be able to do in your new challenge.

INTENT OF CONGRESS

One of the things that we are concerned about, Mr. Secretary, and you are the new kid on the block, so to speak, and there are areas with which you are not exactly familiar. But our concerns as expressed by the chairman and we will express them during the next few months and during the mark up of this bill, are how the Department deals with the intent of Congress, specifically, with report language. One instance, report language we put in last year had to do with the elderly. We have talked about the elderly earlier. Let me quote that paragraph to you.

It has come to the attention of the committee that elder abuse is a growing national problem. Therefore, the committee directs the Secretary to provide $500,000 for demonstration projects in five States in order that older Americans protection services programs can be developed and instituted.

ELDERLY ABUSE

My question, Mr. Secretary, is what steps have been undertaken by your Department in an effort to comply with this report language on elderly abuse?

Secretary BOWEN. Your statement that there may be many areas with which I am unfamiliar is very true. It is like studying for a final exam every night.

Senator ANDREWS. But also my statement about being impressed with your record in Indiana leads us to have the hope, the expectation shall we say, the certainty that there are not many darn areas that you are not going to be well acquainted with very shortly.

Secretary BOWEN. I hope so.

Senator ANDREWS. And that is why rather than have interminable phone calls between my staff and your staff, I felt, since I think I know your concern about elderly abuse to be the same as this committee's, I thought I would ask you what you intended to do in this field since it was specifically mentioned and directed in our report that you do this.

Secretary BOWEN. The Administration on Aging has funded such projects in the past, and they will continue to make funds available on a competitive basis for this type of a project. While it is expected that we will fund elderly abuse projects of the type mentioned in the report, which directed that $500,000 be provided for five programs in 1986, until final decisions regarding the competition for discretionary funds are made, it will not be possible to guarantee a particular number of projects or the level of support.

Senator ANDREWS. Well, let me rephrase the question, Mr. Secretary.

Is your Department going to comply with that specific directive in our report? Are you going to fund five demonstration projects in that many States?

Let me mention first off, North Dakota is not eligible for one of these grants so this is not anything parochial from my standpoint. But I am concerned with this situation on a nationwide basis.

Secretary BOWEN. Twenty applications have been received, and they are in the process of being reviewed. It is my judgement that the five

will be approved, but I am not completely familiar with this particular program.

Senator ANDREWS. But in your own words, you are concerned about the situation of elderly abuse.

Secretary BOWEN. Absolutely.

Senator ANDREWS. And in your own words, you intend to see that we get this funding for these five demonstration projects.

Secretary BOWEN. Within my authority, but again, I will have to check the figures and the program. If there are 20 applicants, and we are instructed to have five programs and to spend $500,000. If that is in our 1986 budget, then it will be done.

Senator ANDREWS. Well, we cannot ask for anything more than that.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

In the 1987 justification of appropriations for the Health Resources and Services Administration, it states in the section regarding health professions educational initiatives which includes geriatrics long-term care programs that are designed to train students and practitioners in problems of the aged, and let me quote.

> In view of projected national surpluses of health professionals by the end of this decade, and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required.

I am coming at this question of what we are going to do with our elderly from a little different direction than our chairman did a moment ago. I find this an interesting comment because when I speak with rural health organizations and constituents from North Dakota, one of their major concerns is that these are the very programs that are not present in rural America.

Can you inform our committee of where these surpluses are occurring and what is happening to this distribution pattern that you mentioned?

Secretary BOWEN. The number of physicians and nurses who are available for practice throughout the Nation is adequate, but a distribution problem still remains. The distribution problem is taking care of itself through the fact that if one area is overcrowded the tendency is to go to an area of need.

UNDERSERVED AREAS

Senator ANDREWS. Well, in a sense. But if you are not used to a place like North Dakota, 40 degrees below zero has a tendency to eliminate the riffraff and discourage others from coming in. Since we are underserved by both nurses and physicians, it would then seem logical following your statement that you have to encourage them to go to this area of underservice, that you would continue to fund those kinds of programs in schools where the students are largely from underserved areas. Would this be an effective way of handling it?

Secretary BOWEN. It would be one way. I would have to ask, "if you could even double the number who are available would they still come?"

Senator ANDREWS. Well, the ones who come from that area, the In-Med Program, where we take Indians from the reservation and put them in medical school, they go back to the reservation. Those students are typically 10 years older than their classmates. But my daughter graduated from medical school a couple of years ago and some of her classmates were these Indians and they were 10 years older, but they were at the top of the class. It took that long to get them caught up. They go back to the reservation.

If you get students from an underserved area in North Dakota, they are going to have a tendency to go back because they understand that area. Similarly, with the other underserved areas.

Could you, Mr. Secretary, tell this committee that because of the shortage in these areas that you will direct the programming of these funds to encourage education in these fields to those universities, those training programs, where these shortages occur? Or do you have a better idea?

Secretary BOWEN. All of the training grants have not been stopped.

Senator ANDREWS. No; you do not have to look in the book, Mr. Secretary. It is just that years ago, over 100 years ago, my grandparents were both physicians. And they practiced in New York City for a couple of years. Frankly, there was no recognition for a woman physician in New York City in 1887. And they went out to Dakota Territory. Now, they graduated from Michigan Medical School. Practiced in New York. Were from New York. And went to Dakota Territory.

We do not find that kind of movement west or whatever into the rural areas now that we had then. We hope to encourage it by taking students from our area, training them and because they know, they understand, they appreciate the values in our area, they would then practice, whether it is nurses or doctors, in our area. And we have looked at this problem.

I have whole counties, Mr. Secretary, who have no doctor. And we try to get them from the Public Health Service. We try to get them—we have people who have to drive 100 miles to get medical attention. We have yet to come up with a better idea than training our own to serve our own.

And we have a great deal of problem finding ourselves in a position where the grants and the other things that would train our young people as nurses and doctors who would have a greater tendency to go back and serve our underserved areas are being cut back.

And the question that I have solely is if you have a better suggestion we would like to hear it. If not, could we have your support for continuing that kind of educational program so that we can produce the doctors and the nurses that can serve our area?

MINORITIES AND SCHOLARSHIPS

Secretary BOWEN. I recognize the need. I want to look into programs for minorities and the scholarships that are available. I believe that we have scholarships and other aid to the students who want to go into medical school. It is based on need.

Senator ANDREWS. I know that. We are talking about a rural location. Let me ask one final question.

Secretary BOWEN. I will look into it, sir.

Senator ANDREWS. Yes; I would appreciate that. And if you have a better suggestion, we would like to know that. But we have not come up with a better solution than that.

A final question that has to do with the problem we have in the reimbursement by the Federal Government of various medical procedures. We have an HMO/doctor relationship in Hettinger, ND, a very small town, but fantastic service. Individuals trained at the best training spots in our country. They have congregated there a group of 16 physicians. People drive for 100 miles around. It is the only hospital really within 100 miles, yet when they do a cataract procedure they are paid by the Federal Government reimbursement one-half as much as they would be paid if they were in Fargo, ND. If you do that same procedure in Fargo, ND, you are paid under the Federal guidelines one-half as much as if you were in Los Angeles.

COSTS OF MEDICAL PRACTICE

One of my close friends, a fraternity brother of mine, is an ophthalmologist in Fargo, ND. He gets one-half as much as his graduating classmates get doing the same procedure in Los Angeles. Cal does not mind. He likes living up there, does a great job, and he is doing all right. But he says whenever he gets his laser fixed, he has to fly the mechanic in from Los Angeles. His costs of practicing are higher in Fargo than the cost of practicing of his friends in Los Angeles, yet they get paid more. And in Hettinger, ND, where you have to have service close to the people to be effective medical service, they are paid even less.

Doctor, could you work toward equalizing these fees? If a person is competent to do an appendectomy and is going to get a Federal fee payment, should he not be paid the same if he does it in West Overshoe, IN, as if he does it in Boston, MA?

Secretary BOWEN. That seems a reasonable suggestion.

Senator ANDREWS. I think it is highly reasonable or I would not have suggested it. And I may, because I anticipated your next statement is going to be the cost of doing business is less in a smaller town. That is why I pointed out my friend who it costs more to get his laser fixed in Fargo, ND, than if he was practicing in Los Angeles.

Secretary BOWEN. There is as much reason to argue the point about rural and urban discrepancies not only on the payment to physicians, but also to the payment to hospitals.

Senator ANDREWS. Absolutely. And I would not back away from that and I am glad you brought it up because if you had not I would have.

Secretary BOWEN. OK. We realize that problem, and there have been some efforts to adjust for these situations. For example, we have created payments for what is called the sole community hospital, which is a hospital located in a rural area, but still the only hospital serving a huge number of miles.

In addition to that, we have what are called the rural referral centers that treat the more complicated cases, comparable to those in the urban areas.

We have also taken into account the wage problem. A rural hospital may have to depend upon city individuals to come to the area to work; so there is a wage adjustment index.

We are working on the problem of discrepancies and not only in geographical areas for payment of physicians, but also differentials between the various specialties. The internists and the family practitioners feel that they get paid less than those who do complicated surgery, in spite of spending essentially the same number of hours doing their work. So that is an unresolved question.

Senator ANDREWS. But we have found in the past that your Department has been, shall we say, less than active and less than responsive in addressing this need and while they have been less than responsive we have had hospitals close in North Dakota where there are not other hospitals within 80 miles to give that kind of service because their rates were forceably kept lower than rates of other hospitals. So your understanding of this problem and your saying that you are working on it is good enough.

We will follow through with other questions down the line in later hearings, Mr. Secretary, because it is critical.

We have an excellent hospital in Williston, ND. It is 100 miles away from the other hospital in Minot, about 90 or 100 miles. And they are paid much less per room per bed by Federal rules than a hospital in Fargo, yet these people in Williston cannot all come to Fargo. They cannot all come to Bismarck. Because making that 4-hour trip, more than that in a blizzard, means medical care denied, and I appreciate your statement that you are addressing that issue and we will look forward to great things coming in the next few months in that area of shall we say equalizing the compensation for medical service, for the hospitals, for the doctors, and the rest. It will mean a great deal in the rural health care, Doctor.

Secretary BOWEN. There are 589 or 21 percent of all the rural hospitals that receive some kind of special treatment, but that still leaves 79 percent that——

Senator ANDREWS. True, but the trouble is that special treatment is often payment at 40 or 50 percent as much as you pay the big city guy. We are just asking for comparability. We do not want an edge. But we do need comparability if we are going to maintain that service, and if we cannot maintain it there are a lot of people who are going to suffer immeasurably because of the lack of service.

Thank you, Doctor. Thank you, Mr. Chairman.

Senator WEICKER. Thank you, Senator Andrews. Senator Rudman.

GRAMM-RUDMAN-HOLLINGS CLARIFICATION

Senator RUDMAN. Mr. Chairman, thank you very much.

I just want to say to the chairman I am delighted he took the opportunity at the appropriate time to correct the Secretary on his, I am sure, inadvertent statement about the effects of the Gramm-Rudman-Hollings bill. I would like to say to the chairman, although he showed a rare lapse of his normal, impeccable good judgment when he did not support the bill, he certainly shows his great studious attitude toward legislation because he obviously understands it better than many who voted for it.

Secretary Bowen, I must say that I am sorry to bring this matter to your attention at this hearing, and quite frankly this has not happened on your watch or on Acting Director Desmarais' watch, but I sat here somewhat stunned to hear that the chairman of the Senate Appropriations Committee cannot get an answer from the agency you have now headed for 9 months. That has little to do with you or your predecessors. It has a lot to do with your bureaucracy, and I find that kind of appalling.

Being a very, very junior Senator from New Hampshire, I estimate my mail might take 4 years to be answered, and I might not even be around to get the answer.

MASSACHUSETTS BLUE CROSS/BLUE SHIELD

So I want to tell you about a situation that I wrote to you about fairly recently, which Mr. Desmarais knows about. It is the quintessential demonstration of the old Yankee adage "if it ain't broke, don't fix it."

You folks, for some reason that astounded most of us, decided that you would award Medicare part B to Massachusetts Blue Cross/Blue Shield. You did it because you thought you could save some money. You awarded it in April and gave them 6 months to gear up for it. So they would now be administering Medicare to Massachusetts, Maine, New Hampshire, and Vermont.

It is an absolutely abysmal mess. I had three people, small suppliers, tell me over the weekend that they were going to have to file a chapter 11. While we sit in this nice, warm comfortable hearing room, these hard-working people are probably going to go to a chapter 11 because they have not been reimbursed for months.

We are not talking about doctors now. We are talking about small equipment suppliers. We are talking about certain clinics. We are talking about various kinds of out-patient services in tiny hospitals in New Hampshire. We are talking about equipment and ambulances and the beneficiaries themselves.

AWARD OF CONTRACT

Now, Secretary Bowen, I have done some digging and I am about to go fairly public with my findings. And, again, I understand these decisions were not made on your watch nor on Dr. Desmarais' watch. But, it is my understanding that at the time this award was made the agency had a rule that said those people in the lower 20 percent of performance would not get new Federal contracts. And yet, I am told that the statistics were there to show that Massachusetts Blue Cross/Blue Shield was in the lower 20 percent but, was given this contract for, I believe, some illusory savings.

Every member of the delegation of the two States wrote to then Secretary Heckler and said this was a very bad idea whose time has not come. They paid about as much attention to us as they would have a gnat on the beach, and here we are with the Massachusetts Blue Cross/Blue Shield Medicare part B contract in a shambles.

Older people in New Hampshire are having trouble buying necessities because they have not been reimbursed. Businesses are ready to go bankrupt. Headlines are in the paper every day.

My question after that diatribe, Mr. Secretary, is how long is it going to take your agency to do what any normal corporation would do and say, "Massachusetts Blue Cross/Blue Shield, you are in default. You have defaulted on your performance. You have breached your contract. We are changing it."

I want to know how long that is going to take. How much more evidence do you need? The gentleman who has the evidence is sitting behind me.

Secretary BOWEN. Henry, please come up to the table.

Senator RUDMAN. He did not make the decision. I know that.

Dr. DESMARAIS. Being originally from the great State of New Hampshire myself, it is not a pleasant situation to discuss. It is an unfortunate situation.

As you know, the reason behind the competition was an efficiency move, to consolidate the areas that would be served by an individual contractor. It was done through competitive bidding. There was an analysis of that competitive bidding.

To get to your question, however, under the terms of any of these contracts including the tristate contract given to Massachusetts—if the contractor's performance over 1 year is not adequate, then that contract may be terminated on default. There are also other avenues available to terminate a contract, but they are at the convenience of the Government. Under those terms, we would have to pay substantial close-out costs for that particular contractor because it would be at our convenience.

CORRECTIVE ACTION

We have been hard at work with the congressional delegation, including yourself, your staff, the regional office in Boston, and the contractor. The contractor has filed a corrective action plan. They are meeting the early targets of that plan.

We have evidence that their performance is improving. We hope that that statistical evidence will soon be translated into improved services for the beneficiaries and the providers in your community.

I am aware that we have extended, because of this unfortunate situation, some advanced payments to individual suppliers in the State of New Hampshire when that seemed warranted. We are doing everything we can, and we intend to continue that. If the Massachusetts contractor does not shape up, the contract will be terminated.

Senator RUDMAN. Well, Dr. Desmarais, I think you would agree that, although the corrective action plan which has just been put into effect is starting to work, the fact is, nobody in the State of New Hampshire or Vermont has felt the results yet. Is that correct?

Dr. DESMARAIS. Well, it may not completely be felt yet, that is correct.

Senator RUDMAN. And you would also agree that this contractor had 6 months after the award of contract to provide the services, am I not correct?

Dr. DESMARAIS. I believe that is correct.

Senator RUDMAN. They had from April until October.

COMPETITIVE BID

Dr. DESMARAIS. But, Senator, this was a competitive bid. We believed we were picking the best bidder under the totality of the bid. The contractor made a number of business errors, for which your constituents have paid, HCFA is now scrambling to hold them accountable for those kinds of business errors.

Senator RUDMAN. I understand the nature of a contract. I understand it is a 1-year agreement, but I would submit to you that anybody who was in gross default of a contract and does not fulfill its obligations under the law of the Commonwealth of Massachusetts and the law of the State of New Hampshire, irrespective of contractual language, could be terminated on the basis of absolute breach. This is true in any contract.

I am going to serve notice to you here and now, and I think, you know me well enough, Dr. Desmarais, to know I am dead serious. I intend this to be fixed and fixed soon or the Government is going to hear about it in a variety of ways, some of which you have not even thought of. I am not saying that in a personal way. What I am saying to Secretary Bowen is that I am sore about this. This is no way for the Federal Government to exercise its responsibilities and either this is going to be fixed soon or there is going to be serious trouble about it.

I am here today to escalate this Medicare nightmare to the level of Senator Weicker's subcommittee, of which I am a member, because this is disgraceful conduct. Not your doing. Not the Secretary's doing. But you are in the unfortunate position of inheriting it, and we want it fixed and we want it fixed soon. I do not want to hear about this for the next few months, because by that time some very good people will have paid a price they should not have to pay due to a mistake made

by this Government. That is just not the way the Government should treat its constituents.

I appreciate the chance to talk to you about it here this morning.

Senator WEICKER. I join the Senator from New Hampshire in his request of your agency that the problem be resolved as early as possible.

DIRECT CARE—AIDS VICTIMS

When the Director of OMB, James Miller, testified before the full Appropriations Committee on the administration's fiscal year 1987 budget, Mr. Miller stated that quote "OMB does not believe it is a Federal responsibility to provide for the care, the direct care, of AIDS victims." End of quote.

Do you agree with that statement?

Secretary BOWEN. I think the Federal Government certainly has a responsibility with respect to AIDS. When it comes down to specific care, I would have to agree that that specific care would have to be shared from the local community on up. The Federal Government I think has the responsibility essentially of doing what they are doing and that is trying to make every effort to find the cause, the cure, and the prevention of the disease. If it comes to stating that for a particular disease the Federal Government should institute total care—I think that is questionable. One might say, "Why not for pneumonia? Why not for typhoid? Why not for each disease that we have?" I think there has to be a limit.

HELP FOR AIDS VICTIMS

Senator WEICKER. I think the answer to the question that you just asked is that if you have pneumonia, you have no problem getting into a hospital. If you have a variety of diseases, you have no problem getting into a hospital, or somebody to go in and take care of you.

Now, what we initiated in the appropriations for fiscal year 1986 was a $16 million pilot program to assist cities in the care of these people.

Now, Dr. Bowen, I point out to you that when you get to the point where the church cannot even get its members to agree to help, and as you recall, that was the Catholic church in the city of New York, I believe, where they tried to make provision for a facility to care for these AIDS patients and that was turned back. Obviously, there is a very special problem here as to the care of these people. And, of course, that $16 million was rescinded.

The $2 million that Senator D'Amato put in for a hotline to get information, that was rescinded.

In other words, I do not think that anybody is contemplating some sort of care that is not totally necessary in light of the unique circumstances of this particular illness where nobody wants to take care of these people. It is hard for them to find a facility to tend to their ailments.

I might add parenthetically that if the administration believes the only role for the Federal Government is to provide funding for re-

search then why is the Department of Health and Human Services proposing a 1986 rescission of $14 million in vaccine development?

Secretary BOWEN. Sir, I did not mean that the Federal Government is not doing other things. I could list several programs through which AIDS victims are receiving help—for example, through Medicaid. They are Medicaid eligible, obviously when they have no other means of taking care of themselves. They are also Medicare eligible once they become disabled.

The Veterans' Administration also is caring for a great number of them. Further, the Robert Wood Johnson has come out with a $17 million grant to assist in caring for them. We are concerned with the public's expectations that all AIDS patients be treated at Federal Government expense.

As I mentioned, I think creating a special benefit could be dangerous——

Senator WEICKER. I think the way things stand now, really the way things stand now, nobody to care for these people—you are well aware of the fatality statistics—and yet very little has been done in this regard.

The committee will again, I can assure you, take a look at this problem. I think we are all well aware of the fact that basically there are three areas of principal concern. No. 1, the short-term assistance in the sense of developing some form of chemotherapy which at least will slow down the disease from continuing or increasing in a person's body or its transmission.

No. 2, the vaccine would go ahead and eliminate it. But then, as I say, the short-term problem, and it is probably a short-term problem if we succeed in these other two areas, what do you do with these people? And that has posed a real problem to institutions throughout the country.

I might add, I think that all of us on the committee feel of one mind here, Dr. Bowen. We all understand full well your recent accession to the position of Secretary. And we do not want to in any way be unfair in terms of our questioning. On the other hand, I want to put on notice those that follow you in the next several days who have been, who are well aware of all the facts and the background and the previous appropriations hearings, that I doubt that the questioning is going to be as charitable, in the sense of carrying out the congressional mandate, or in the sense of defending this administration's budget.

NIH CUTS

At a time of unprecedented biomedical accomplishment, the President's fiscal year 1987 proposed budget cuts the National Institutes of Health from fiscal year 1986 appropriated levels by more than $400 million; reduces new grants by 1,000, as you correctly stated, down to 5,140 from 6,100; reduces the number of trainees by over 1,000; it reduces the number of congressional-mandated employees by over 850; it zeroes out one of the most important programs of innovative basic research, which is a direct grant to the university to support new innovative research.

And my question, very simply, to you, Mr. Secretary, is do you support these cuts?

Secretary BOWEN. It is difficult to say that we absolutely support the cuts. The Gramm-Rudman-Hollings Act does enter into the picture, because it has provided a 5-year framework for the reduction of total spending by 1991. We have to establish the priorities and in our best judgment these are the priorities that come within those——

Senator WEICKER. Excuse me. But are you establishing the priorities within your agency, or are you seeking to establish the priorities within the entire framework, in other words, of Gramm-Rudman-Hollings?

Secretary BOWEN. Both. We certainly are a part of the administration, and we need to have an overall target to meet. Within the targets that are given us, it is our responsibility to establish priorities.

Senator WEICKER. See, this gets to the question that Senator Hatfield asked in his opening remarks. You know, you are leveling yourself here while, let us say, the defense research soars, soars. And, of course, the job of our committee is we are not constrained just to work things around within your Department. We have that whole field out there in front of us.

And I would hope, and I think I speak for Senator Hatfield in this regard, that in this position of Secretary of Health and Human Services that you would be a primary advocate for matters under your jurisdiction. You do not have to worry about the Defense Department. They have plenty of spokesmen over there. They do not need you. Health and Human Services needs you. And then fine, if somebody else knocks you down, so be it. But this is a disastrous budget as far as NIH is concerned. Absolutely disastrous.

Another thing I would like to state and I do not want to hear any of your advisors advising you otherwise. You indicated what the costs would be of each new grant for a 3-year period. The administration was well aware of that. You were well aware of that when we negotiated those figures with Dave Stockman. You knew what the 3-year costs were. Actually, we had 6,200, 6,200, so we negotiated down. One of the reasons why we did was the very point that you raised. So I do not want to hear the fact that this is going to cost money down the years. We knew it was going to cost money down the years. The administration knew it was going to cost money down the years when we negotiated this settlement.

Secretary BOWEN. We will make every effort to keep the quality and the productivity as high as we possibly can.

Senator WEICKER. I have one last question and then I have other questions for submission to the record.

PROTECTION AND ADVOCACY SERVICES

And that last question is, I introduced legislation in the Senate to provide protection and advocacy services for the mentally ill. This bill was passed by the Senate. A similar bill was passed by the House. And $10 million was appropriated for the program in the Labor-HHS appropriations bill for fiscal 1986.

I might add, the administration has assured me of its support for this bill. Can you tell me why Health and Human Services' budget request proposed to rescind all of the $10 million?

Secretary BOWEN. I would like to call on one of my staff.

Mr. BELDON. The rescission being proposed is for $9.6 million. The $10 million that was appropriated—$9.6 million after sequestering—cannot be obligated until legislation has been enacted.

Senator WEICKER. Well, what if the legislation does pass, which is very possible, as a matter of fact, within the next couple of weeks. What are you going to do?

Mr. BELDON. At the present time, we are proposing a rescission.

Senator WEICKER. You do not think it is a rather strange proposal by the administration who assured me that they were supportive of the legislation?

Mr. BELDON. I cannot comment on that.

Senator WEICKER. Hey, we want that kind of support? If you do not have anything to do, I tell you, you will not be around very long. I do not understand that at all.

I have to repeat, after very difficult negotiations over a wide variety of things, I was assured of the administration's support for that legislation. And the legislation, as a matter of fact, only awaits conference, and signing into law. But when I see that the rescission is for all the money, I wonder what is going on.

Secretary BOWEN. Those funds were appropriated in 1986, but Congress has yet to complete approval of authorizing legislation. In the rescission we are asking Congress to reexamine making the appropriation in light of no authority to spend these funds in fiscal year 1986.

Senator WEICKER. I have further questions for response to the record and, as I said, I do look forward to working with you, Dr. Bowen, in the weeks ahead.

Senator Proxmire.

Senator PROXMIRE. Dr. Bowen, it is a great pleasure to welcome you to the committee. I am the ranking Member of this subcommittee, and I know of your distinguished record. You have been a coroner. You have been a State legislator. You have been a very distinguished Governor. And now you are a Secretary. It is hard to know what to call you. Doctor? Mister? Mr. Secretary? Majority leader? You were majority leader of the Indiana House I understand?

Secretary BOWEN. Speaker.

Senator PROXMIRE. Speaker. That is even better.

At any rate, it is great to have you here and I am sure you will do a distinguished job in the Cabinet. And I think you will find, as Senator Hatfield said, that in working with the chairman of this subcommittee you will be working with a kindred spirit, a real champion of your cause.

DISPARITY BETWEEN NSF AND NIH BUDGETS

Mr. Secretary, the administration is proposing a cut in fiscal year 1987 of about 8 percent in the fiscal year 1986 pre-Gramm-Rudman-Hollings NIH budget. That is a cut of about 3.7 percent of the 1986 budget minus sequestered funds.

On the other hand, I understand that the National Science Foundation budget would increase by 8 percent under the President's proposals with the NSF's biological, behavioral, and social science directorate receiving a 9-percent increase. NSF has also gotten about 9 percent of my golden fleece awards.

As one of the participants in the budget formulation process, can you give us any insights into why the NSF budget is going up while the NIH budget goes down?

Secretary BOWEN. I think one of the reasons is that the NSF budget takes in the need for a lot of hardware and equipment that are a lot more expensive. The NIH budget did go down some, and again, that is within the 5-year framework of getting a balanced budget by 1991. We will make every effort to make up for whatever deficiencies there are in moneys with increased quality and productivity.

We can say with pride that there are three Nobel Prize winners on the staff of NIH and there are 63 other Nobel Prize winners who have received NIH support since World War II.

Senator PROXMIRE. I am very impressed by that number. When you cited 63 Nobel Prize winners earlier, I was present but I had to leave and come back. I did not realize that there were that many Nobel Prize winners in the biomedical field in total. You must have pulled in a few ringers.

Secretary BOWEN. I was equally surprised.

Senator PROXMIRE. If there were two Nobel laureates every year, that would be 44 years of Nobel Prize winners receiving grants from the Department. Amazing.

Secretary BOWEN. I will double check it, but I verified that number previously.

Senator PROXMIRE. Does that include non-American Nobel Prize winners?

Secretary BOWEN. Yes; it does.

Senator PROXMIRE. It does. Well, that is marvelous, and it is certainly a great distinction.

At any rate, your response is that because of the fact that the NIH budget has a great deal of hardware——

Secretary BOWEN. No; the National Science Foundation.

Senator PROXMIRE. I beg your pardon, I beg your pardon.

Secretary BOWEN. The National Science Foundation.

Senator PROXMIRE. Because the National Science Foundation——

NSF/NIH BUDGET CUTS

Secretary BOWEN. The National Science Foundation's focus is in the area of engineering and computer research which requires expensive hardware.

Senator PROXMIRE. Well, we will check that out, but it seems to me that hardware acquisition is the kind of thing that is easier to postpone than some of this other activity.

I have been asked by Senator Inouye, who is a Member of the subcommittee, but could not be here, to raise one question that he feels very strongly about, and wants asked orally.

NATIONAL CENTER FOR NURSING RESEARCH

This is the question from Senator Inouye. In 1985 your predecessor, Mrs. Heckler, established a Center for Nursing Research in the Division of Nursing. However, no funds were made available by the administration to fund the Center. The Congress mandated the establishment of a National Center for Nursing Research at NIH in Public Law 99–158 and now the administration proposes a total rescission of the $5 million appropriated by Congress to fund the new Center.

What is your rationale for proposing this rescission in light of a clear congressional mandate through the authorization and appropriation of funds for the National Center for Nursing Research and in light of the serious evidence of need for nursing research funds according to a 1985 Institute of Medicine study?

Secretary BOWEN. The number of nursing personnel is adequate at the present time; as are the number of physicians. It seems like poor policy to increase the number, when an adequate supply can be found. The other reason is that the Center is not totally ready to begin functioning at the present time. If the Congress wants it to function in spite of the rescission, then the Public Health Service is in position to go ahead. They are seeking a Director and will be ready to go if the rescission is not approved.

Senator PROXMIRE. Thank you, Mr. Secretary.

Mr. Secretary, for the record would you document or have your staff document your response regarding the number of nurses. The number of nurses is adequate at the present time, you say?

Secretary BOWEN. Yes; we can do that.

Senator PROXMIRE. That would be helpful.

Secretary BOWEN. I have the figures here someplace.

Senator PROXMIRE. And then can you tell me when the National Center for Nursing Research will be operational?

Secretary BOWEN. I believe that it will be ready in late spring or early summer.

Senator PROXMIRE. All right, sir.

Mr. Chairman, I have one or two questions for the record.

I want to thank you very much, Mr. Secretary.

Secretary BOWEN. Thank you.

[The information follows:]

NURSE SUPPLY

Evidence presented in the fifth "Report to the Congress on the Status of Health Personnel in the United States" found no aggregate imbalance between nurse supply and requirement in the foreseeable future.

Taking into account the future projections of requirements and the available supply, given the anticipated flow of graduates and current trends in the work patterns of the registered and licensed practical nurse population, the following picture emerges of the full-time equivalent nurse supply and requirements for 1990 and 2000:

	1990	2000
Registered nurse:		
Supply	1,454,000	1,750,000
Historical trend-based requirements	1,414,000	1,683,000
Criteria-based requirements (lower bound)	1,733,000	2,328,000
Licensed practical/vocational:		
Nurse supply	608,000	756,000
Historical trend-based requirements	527,000	720,000
Criteria-based requirements (lower bound)	321,000	423,000

From these data, it would appear that no real imbalances exist between the potential available supply and the historical trend-based requirements projections for registered nurses. The criteria-based model presents a somewhat different picture in that requirements for registered nurses are somewhat higher than the potential supply. In the main, however, the differences between the two requirements projections can be attributed to a large extent to concerns leading to fundamental changes in the objectives for nursing care in such areas as nursing homes and community health. Thus, in examining the differences between the supply and the criteria-based requirements, consideration should be given to the extent to which the premises and goals upon which these requirements are based could and will be achieved.

For licensed practical nurses, conclusions drawn from the historical trend-based model find that by 2000 supply and requirements appear to be in balance, although there would be an oversupply for 1990. Under the assumptions in the criteria-based model, however, the potential supply of licensed practical nurses would exceed the requirements. Nursing groups, both professional and practical, envision fundamental changes for practical nurses in the future. The impact of these on supply and requirements is dependent on the degree to which these changes are accepted and can be implemented.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Mr. Secretary, I thank you very much. There will be questions from this and other Senators for response to the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

Legislation on Appropriations

Question: Mr. Secretary, I have consistently objected to including legislative proposals as part of any budget request. Your Department's budget is filled with legislative proposals and assumed budget savings, particularly in the entitlement programs.

- How much would need to be added to the Health and Human Services budget request if no legislative savings are assumed?

- Aren't legislative proposals just a device to make the President's Budget -- and the deficit -- appear billions of dollars lower than they really are?

Answer: Savings proposals requiring congressional action included in the budget request for Labor/HHS programs total $1.4 billion. Those proposals notsent to Congress with the budget, but proposed for later transmittal, for Labor/HHS programs would save an additional $1.4 billion. If you include the trust fund proposals, which do not require appropriations action, the total legislative proposals would equal $5.0 billion. This total does not include income generating proposals, that are also included in our savings projections.

Regulatory proposals would add another $1.8 billion in savings.

The savings proposals are included in the President's Budget to bring the budget into line with the Gramm-Rudman-Hollings mandated deficit level of $144 billion for fiscal year 1987. They are submitted to lower Federal spending and to inform the Congress of program revisions which the Administration considers appropriate. The proposals are designed to place limitations on the use of Federal funds and follow the pattern of similar legislation enacted in appropriations bills.

AIDS

Question: The Department has proposed centralizing funding for AIDS directly into the Office of the Assistant Secretary for Health; combining the AIDS funds previously appropriated for the Centers for Disease Control, the Alcohol, Drug Abuse, and Mental Health Administration, and the National Institutes of Health under one office. What is the advantage of centralizing all of the funding in one office?

Answer: Consolidation would enable PHS to better highlight the total level of resources being devoted to this top public health priority, better plan and coordinate the AIDS control effort, and better ensure that PHS supports the most important research and prevention priorities.

Centralization of the AIDS resources would also provide PHS with a mechanism to better monitor AIDS scientific research requirements and to be more responsive to agency requests for redirection of AIDS resources. This would increase resource flexibility and interaction within the multi-faceted AIDS program.

Also being requested is authorization (1% transfer authority from other lower priority programs) that would allow PHS to increase AIDS resources for PHS agencies as scientific breakthroughs occur and as new and urgent opportunities are identified. This would ensure that PHS can do everything possible to respond to this major problem.

Question: Won't this create additional bureaucratic layers between available funds and the research scientists?

Answer: No. We are not creating an additional layer, but are simply adding a full-time PHS AIDS Coordinator to assist the Assistant Secretary for Health and the existing PHS AIDS Executive Task Force. Dr. Walter Dowdle has been appointed as the PHS AIDS Coordinator and will be devoting his full time and attention to the overall coordination of PHS AIDS activities. While some minor additional financial management paperwork will be created, we regard the benefits from better overall coordination and flexibility to be worth this.

Question: What will happen to the priorities already established and in some cases begun in FY 1986?

Answer: PHS will continue to provide support to these AIDS research priorities established for FY 1986 and currently plan to continue those activities in FY 1987, unless, as stated above, new scientific breakthroughs and opportunities occur which make our current AIDS research plan outdated.

Question: On what basis would funds be allocated for the various AIDS efforts?

Answer: Operations responsibility for AIDS activities will continue to reside in the individual agencies involved. We are currently planning to allocate the resources to these agencies consistent with the distribution presented in our 1987 budget request (i.e., $45,409,000 for CDC, $142,990,000 for NIH, $13,733,000 for ADAMHA, and $1,350,000 for OASH). However, final FY 1987 allocations to the individual agencies will be based on their AIDS operational plan approved at that time through the PHS AIDS Executive Task Force, and will be allocated through reimbursable agreements.

Question: In the past, as the need arose for additional AIDS funding, the Department has asked the Congress to permit a reprogramming of funds from other activities. Under your consolidation proposal, would you still request a reprogramming, or would you simply eliminate such activities as the hotline and community demonstrations in order to put additional funding into research, without consulting the Congress?

Answer: The Assistant Secretary for Health currently intends

to operate the proposed consolidated AIDS account for FY 1987 in such a manner that reprogrammings would not be requested, as this would seem to defeat the purpose of the proposal which is to increase PHS's flexibility to manage the total AIDS effort and to be more responsive to shifts in research emphasis as they may occur.

As you know, we have asked that $15.3 million for AIDS service delivery demonstration projects and approximately $2 million for an expanded AIDS hotline be rescinded in FY 1986. If the proposed rescission is rejected by Congress, these programs would be funded in FY 1986.

Question: Isn't this simply a method by which you could eliminate certain AIDS efforts which the Congress supports but which you do not?

Answer: No, the proposal is not an attempt to circumvent supporting efforts which the Congress supports. Rather, our proposal is designed to increase our flexibility to respond to changing priorities resulting from new opportunities including specific scientific breakthroughs in AIDS research and prevention. As for program eliminations, PHS would seek Congressional Appropriations Committee approval before eliminating any program for which specific funding was provided.

INFANT MORTALITY

Question. Despite large reductions in infant mortality in the United States in in recent years, 16 other countries still have lower rates.

Why does our infant mortality rate continue to be so high?

Answer. In 1982, the U.S. ranked 14th in infant mortality among countries with at least 1,000,000 population with complete counts of live births and infant deaths. Historically, the U.S. has maintained this approximate ranking for two decades. There is wide variation in the U.S. infant mortality rate (IMR) according to sociodemographic characteristics. For example, in a 1980 study from 9 States, the Centers for Disease Control found that the IMR among white women, ages 20 and over with 13 or more years education, was 7.4/1000 live births. This compares favorably with the Scandinavian countries (e.g., Sweden 6.9; Finland 7.6; Norway 8.1). Furthermore, several studies have shown that the higher IMR in the United States is due to a higher incidence of low birthweight. On a birthweight specific basis the U.S. has one of the lowest infant mortality rates in the world.

Question. What is being done to lower it?

Answer.

Service Programs

- The Maternal and Child Health (MCH) Services Block Grant authorizes annual appropriations for allocation to 57 eligible jurisdictions and provides each State the authority to allocate resources based upon its own needs assessments and priorities in order to assure access to maternal health services of good quality and to reduce infant mortality - especially by providing prenatal care and preventive services. In addition, the MCH

program supports a wide range of activities to strengthen the capacity of the States to improve health status outcomes for mothers and children including the awarding of grants for special projects of regional and national significance.

° The National Health Service Corps (NHSC) and the MCH program are working jointly to identify obstetric and pediatric underserved areas in the U.S. to place obstetricians and pediatricians to provide direct services in medically underserved at risk areas.

° Community Health Centers (CHC) and Migrant Health projects provide prenatal care to medically underserved pregnant women and are implementing a perinatal initiative to ensure delivery of high quality maternal and infant health services. Recent activities include publication and promotion of guidance materials for development of perinatal services in community health centers and stimulating the development of service systems in rural areas.

° The Indian Health Service, working with tribal health departments, private practitioners and national professional organizations, provides comprehensive maternal and child health services. Emphasis is on early identification of pregnant women and entrance to care, especially for the teenage population. There has also been emphasis on regionalization of perinatal care to assure appropriate levels of care. At least partly as a result of these activities, the infant mortality rate for Native Americans dropped from 13.2 in 1980 to a provisional rate of 10.0 in 1984.

Demonstrations

° Grants for special projects of regional and national significance (SPRANS) are funded by DMCH in order to improve health status outcomes for mothers and children. In FY 1985, approximately $3 million new dollars were awarded for projects focused on pregnancy and infant care targeting gaps in the service system ultimately to high risk populations. The projects focus on aspects such as tracking mechanisms, low birthweight prevention, and a mechanism for delivering services in rural areas. FY 1986 efforts relative to infant mortality/low birthweight will continue to receive high priority.

Research

° The National Institute of Child Health and Human Development (NICHD) has implemented a special research initiative focused on the prevention of low birthweight and its etiology. Current activities include:

- Supporting a multi-center clinical trial to establish whether asymptomatic genitourinary infections induce premature labor and the effect of antibiotic treatment on these infections in preventing maturity.

- Organizing networks of 6-10 leading obstetric maternal-fetal medicine units and 6-10 neonatal intensive care units that will be established to facilitate conduct of clinical trials of new therapies through use of common protocols to translate research results into clinical interventions in such areas as prevention

and management of premature rupture of fetal membranes, management of premature labor, and management of multiple pregnancies.

° The Division of Maternal and Child Health is supporting studies related to utilization of prenatal care.

- one to determine whether differing levels of Medicaid/AFDC coverage affect use,

- another to develop specific methodologies to investigate behavioral issues associated with entering prenatal care.

Data Efforts

° A national system which links infant death and birth records is crucial to our ability to effectively monitor

Question. Are you concerned that by cutting and block-granting the funds for community health centers, you will be limiting the availability of prenatal services for poor women and possibly contributing to our infant mortality rate?

Answer. I believe that including the Community Health Center program in the expanded Primary Care Block Grant would enhance the availability of prenatal services for poor women since it would contribute to a more rational and efficient use of resources at the local level, where the services are actually delivered.

It is logical to assume that the proposed rescission for Community Health Centers would result in some diminished availability of prenatal services for poor women. However, since the factors contributing to the infant mortality rate are so complex, I am reluctant to hazard a guess regarding what kind of impact that any funding level for Community Health Centers might have on the national infant mortality rate.

VOCATIONAL REHABILITATION AND THE INSPECTOR GENERAL

Question. Mr. Secretary, last year I discovered that Inspector General audits were disallowing Federal reimbursement for vocational and educational activities in institutions for the mentally retarded. Yet these same activities were a requirement for receiving Medicaid dollars from the Health Care Financing Administration. I thought the conflict had been resolved with the Inspector General's office but now I understand HCFA is disallowing reimbursement for vocational and educational services. What is the Department's position on this issue? Do you or don't you reimburse State institutions for these services?

Answer. Medicaid regulations (42 CFR 441.13(b)) include a longstanding prohibition against Medicaid payments to institutions for the mentally retarded for vocational training and educational activities. The intent is to focus Medicaid funding on health care and avoid diverting Medicaid program dollars to unallowable, non-medical educational and vocational costs that are the responsibility of State or other Federal programs.

The Inspector General agreed last year to discontinue further audits of educational and vocational services because of disagreements by States as to which services were subject to the exclusion. HCFA undertook to issue clarifying instructions on this issue.

In the case of education and related services, HCFA took the position that Public Law 94-142 (The Education of the Handicapped Children Act of 1975) makes Federal education funds available only to States which ensure each handicapped child under age 22 a free and appropriate public education. As specified in the Department of Education's regulations, this law encompasses education and vocational training suited to each child's needs. HCFA drafted an instruction drawing this distinction and discussed it with an advisory group comprised mainly of State Medicaid Directors. The group agreed on a policy and in September 1985, HCFA issued revised guidelines to help States distinguish between reimbursable ICF/MR services and excluded education services.

HCFA is currently in the process of consulting with the same advisory group on a clarified policy relating to the vocational training exclusion.

Out Year Cost of Short-term Savings

Question: Mr. Secretary, I am very concerned about the out-year cost of the short-term savings proposed in this year's budget. For example: any cuts made today in

Community Health Centers
NIH research
Immunization programs
Health professions training, etc.

are going to wind up costing us billions of dollars tomorrow,

- o Would you agree that the dollars spent on the HHS programs are an investment in our future?

- o What are your priorities, as the new Secretary, for the future of HHS, and does this year's budget request reflect these priorities?

- o If so, how?

Answer: When we formulated the fiscal year 1987 budget, we considered the effect on the out-years. We do not feel that the reductions we propose will have an adverse affect in future years.

For example, many of the cuts in fiscal year 1986 are related to program terminations requested in fiscal year 1987.

- o The Community Services Block Grant where we felt the funding in a large part duplicative.

- The Work Incentive program where we are substituting the Work Opportunities program (an entitlement) that we feel is a much more helpful program.

- The Health Professions Education program where there are sufficient health professionals in the market place now, and further increases are not required.

As I have stated before one of my greatest priorities is catastrophic health care insurance. The elderly have a right not to worry about financial ruin due to ill health.

I would divide my priorities into three categories:

First,
- — long-term care,
- — medical liaibility/malpractice/defensive medicine
- — quality/access "competition, capitation & voucherization,
- -- welfare reform — ending the cycle of dependency,
  - teenage pregnancy
  - child support enforcement & adoption
  - family values

Second in importance,
- -- new drugs approvals -- speeding up the process,
- -- Prevention/treatment of acute new diseases (Reyes syndrome, herpes, AIDS, Alzheimer's vaccine),
- — Minority Health Task Force -- issues raised,
- -- prevention (related to lifestyle (self regulation) -- smoking,
- -- violence, suicides, accidents,
- -- food safety,
- -- elimination of three-day stay in hospital before nursing home (Medicare),

And, as a third priority,
- -- Graduate Medical Education and specialities,
- -- physician payment, assignment, etc.,
- -- Medicaid, health care for the poor,
- -- homeless,
- -- ensure equal treatment of beneficiaries, providers, & taxpayers.

ICF/MR REGULATIONS

Question. The regulations to implement the ICF/MR (Intermediate Care Facilities for the Mentally Retarded) are 12 years old now. For the last three years your predecessor, Mrs. Heckler, indicated that HHS would be issuing new regulations "any day now" to update the standards for residential facilities. What is the status of these regulations?

Answer. The proposed revisions to the Standards for Intermediate Care Facilities for the Mentally Retarded (ICF/MR) were published in the Federal Register on March 4, 1986. The comment period extends to May 5, 1986.

We are proposing a general revision of the standards designed to increase the focus on the provision of active treatment services to clients, clarify Federal requirements, maintain essential client protections, and to provide State survey agencies with a more accurate mechanism for assessing quality of care.

The proposed revisions to the ICF/MR regulations intend to ensure that clients are provided quality care; and that facilities are relieved of the duplicative requirements contained in the current regulations and thus reduce the operating costs.

As these proposed changes shift the focus from the institution to the client, we believe State surveyors will be in a better position to determine whether active treatment actually occurs for each client.

This determination is important to ensure that those who work with clients deliver accountable, habilitative services that result in the client's growth and development and that result in more effective expenditure for Medicaid dollars in the ICF/MR setting.

Indirect Costs

Question. The Department of Health and Human Services research budget proposal assumes OMB's revision of Circular A-21 that would impose a cap on indirect administrative costs for universities at 20 percent for FY 1987. I understand that the national average for these indirect costs is 26 percent. How was the 20 percent cap in FY 1987 determined?

Answer. The reduction in the allowance for administrative overhead from 26 percent in fiscal year 1986 to 20 percent in fiscal year 1987 is based on a compromise from the Office of the Inspector General's recommendation to reduce the departmental administration component of indirect costs by 8 percentage points, from the current level of 15 percent of modified total directs costs to 7 percent. It was the judgment of the Inspector General that, although departmental administration represents the fastest growing portion of indirect costs, the activity is not well-documented and provides little or no benefits to research.

Question. I understand all universities do not account for their indirect costs in the same way and that capping these costs will affect some institutions disproportionately. Do you have any evidence that this is not the case? How do you plan to deal with this problem?

Answer. Each institution accounts for its indirect costs differently. Two institutions with the same indirect cost rate could vary in the proportion of each component making up indirect costs. Implementation of a cap on indirect administrative costs would, in fact, affect each institution differently depending on its proportion of administrative costs, as a component of indirect costs, to direct costs.

Though this policy will affect some institutions disproportionately, we believe it provides a uniform policy of reimbursing for costs associated with non-research administrative overhead functions.

Question. Why has your Department adopted this provision for FY 1987 while all other agencies have chosen to delay impelementation for one year as authorized in OMB's proposal?

Answer. The Deparrment of Health and Human Services has proposed an early implementation date for this policy as a means of freeing up additional resources for the direct cost component of biomedical research. The fiscal year 1987 budget request was developed assuming a start date of October 1, 1986.

HEALTH PROFESSIONS AND NURSE TRAINING

Question. Last fall, the President signed legislation authorizing the health professions training programs, and late summer he signed legislation authorizing nurse training programs for three years. Now just a few months later, you are proposing to rescind more than half of the 1986 appropriations and to cut the funding for all of these programs in 1987 from $227 million to $3 million.

Why are you proposing such massive cuts in these programs?

Answer. In its reevaluation of competing priorities, the Administration was mindful that the past twenty years of Federal support had built and stabilized an infrastructure that should enable the institutions to continue health professions and nurse training programs into the future. We believe the initiative and interest generated by the Federal start-up grants will be maintained by the colleges, universities, and hospitals that are responsible for training health personnel.

Question. What consideration have you given to those minority and/or economically disadvantaged students who are dependent on these programs for their pursuit of a health professions career?

Answer. The Administration was mindful of the need for financial assistance to minority and economically disadvantaged students. Repaid loan monies to health professions and nursing schools will be available and will enable schools to continue providing assistance to minority and economically disadvantaged students. Cumulative Federal contributions to health professions and nursing student loan funds have put in place a foundation of Federal health professions student aid for economically disadvantaged students which will amount to approximately $67 million in ~~FY 1986~~ and in FY 1987, and will assist approximately 37,600 students in each year.

Question. What do you suggest we do about those regions of the country served by Area Health Education Centers which have no other resource for medical assistance?

Answer. AHEC's mission has always been to assist in organizing and systematizing health professions resources in the community to meet health professions educational needs. They have done this by

bridging activities in the universities and academic health sciences centers with those of the community. The AHEC program is required, by law, to have an increasing cost sharing component built in so that eventually fiscal responsibility can be assumed by state and local entities.

Question. What will happen to the training we are finally beginning to provide in geriatrics (as you know, there is a great need to train physicians) to be better prepared for the future growth of our elderly population?

Answer. We believe that competence in health care for the aged should be fostered in the total health care system and that this task is the responsibility of the health professions education system as a whole, with action by the schools, professional associations, and accreditation authorities.

BLOCK GRANTING COMMUNITY HEALTH AND FAMILY PLANNING

Question. Mr. Secretary, when you testified before the Senate Finance Committee during your confirmation hearings, you stated that you "believe in family planning and you believe government expenditures to assist low and moderate income people are proper and are a wise use of government funds."

Do you believe the Administration's annual attempt to block grant the funding for Community Health Centers, Migrant programs, Black Lung and Family Planning services is a proper and wise way of funding these services?

Answer. We continue to pursue the consolidation of these programs under the leadership of State health officials in order to better target resources for overall primary care services in a more comprehensive manner.

Question. Are you concerned that by eliminating individual funding for these programs and allowing the States to distribute the money as they see fit, there will be no guarantee all of these services will continue to be provided, much less funded at their current level?

Answer. To the contrary, I believe that by utilizing the block grant approach we can better assure more efficient and effective use of available resources, Federal, State, local government and private. States have been very successful in managing the several health block grant programs that were initiated in 1981. Resources continue to be channeled to where there are needs.

Medicare and Catastrophic Care

Question: Mr. Secretary, you have proposed restructuring the Medicare benefit package to provide catastrophic acute in-patient and out-patient care to Medicare beneficiaries in a cost neutral manner.

- Would you briefly outline your proposal and indicate what legislative changes would be necessary to implement your plan?

Answer: During his State of the Union Address, President Reagan requested that HHS "report to me by year-end with reommendations on how the private sector and Government can work together to address the problems of affordable insurance for those whose life savings would otherwise be threatened when catastrophic illness strikes."

We have moved quickly to implement this mandate by setting up three technical working groups within the Department to examine the wide range of issues inherent in any new social insurance policy.

In addition to these internal Committees, we are in the process of establishing an advisory Committee composed of representatives from providers, beneficiaries, and the insurance industry. The purpose of this Committee is to insure that the concerns of a broad range of groups are heard and considered as we deliberate this important policy.

Using the Committee structure I have outlined above, we intend to prepare a report on the various options for catastrophic coverage by December 1986. At that time we will know the specific proposals and will submit to you the legislative changes that would be required to implement the plan.

Work Incentive Program

More than Half the funds available under the Work Incentive Program have now been redirected by States into demonstration projects that appear very similar to the king of "workfare" program advocated by the Administration.

Question. Why does the Administration keep referring to the GAO Report as evidence the WIN program doesn't work when in fact only 13 States still run programs of the type that existed at the time of the 1982 GAO study.

Answer. The Administration believes that various facets of the Regular WIN program--that form of WIN in effect in 43 States in 1982 and currently in effect in 28 States and other jurisdictions--render the program ineffective and justify its elimination. These include:

- Dual Agency Administration--28 States and jurisdictions still share responsibility between the State welfare and employment agencies. This cumbersome approach fails to locate responsibility for reducing dependency in State welfare agencies which have the greatest knowledge of AFDC recipients' needs.
- Registration--A significant percentage of regular WIN funding simply pays for registering people--not for job search or actual work experience.

-- Lack of Mandatory Participation Requirement for WIN Registrants--A high percentage of regular WIN registrants at any point in time are unassigned to active program activities.

The 1982 GAO study cited additional problems with the regular WIN program. The Administration continues to cite this study because of its belief that the deficiencies and issues raised therein bring into further question the program's effectiveness.

The Administration believes that its proposed Work Opportunities Initiative would better address these issues of program effectiveness and remove existing barriers to more effective work alternatives and would require every State, for the first time, to have work programs with strong participation requirements and a focus on real work activities to insure that participation produces real results.

Question. What rationale do you have for proposing the elimination of the program -- to take place immediately through rescission -- only to propose legislation to require States to reestablish the program?

Answer. The Work Opportunities legislation being proposed by the Administration does not reestablish the WIN program. Instead, it establishes a new approach to work activities as part of the AFDC program, an approach which focuses on job search and mandatory participation in real work activities to enhance welfare recipients' employability and earnings.

Some States currently are operating, through their welfare agencies, job search, work experience and related work activities (under the WIN Demonstration or related AFDC authorities) which would be considered allowable under the Work Opportunities Initiative. The Administration believes that such allowable activities would be continued, in most cases, under the new initiative.

Since Work Opportunities will be funded under AFDC beginning in FY 1987, the Administration has proposed to complete the phase out of WIN in FY 1986, by rescinding fourth quarter funds.

Question: What incentive is there for Congress to enact your legislative proposal when the President himself has announced the Administration's study of the welfare system won't be completed until December of 1986?

Answer: While I cannot prejudge the results of the Domestic Policy Council's study, there is no doubt that work will be a key aspect of its proposals. Strengthening work requirements for welfare recipients is a major goal of this Administration and it is an important aspect of welfare reform. In his State of the Union message, in which he announced that there would be a study of welfare programs, the President stated: "We should do nothing to degrade the moral value of work and we should

judge the success of welfare by how many people become independent of it."

We are seeing more and more reports about the benefits of work programs for welfare recipients. They provide participants with the tools and motivation that they need to become employed. They also bolster morale of participants, and benefit the community by providing needed public services. Congress' approval of our work proposal will ensure that able-bodied welfare recipients have the opportunity to regain economic self-sufficiency through work.

Eliminating the Community Services Block Grant

Question. Mr. Secretary, as you know, the Community Services Block Grant funds community action agencies which provide anti-poverty services to over half a million people. Yet this year's budget rquest eliminates all funding for this program. According to your written statement, "the Department proposes that States use other sources of funding, including the Social Services Block Grant, to support those community services activities which are of the highest priority and most effective."

What evidence do you have that the States will in fact pick up the slack?

Answer. In proposing termination of the Community Services Block Grant (CSBG), we are not implying that community action agencies (CAAs) will be able to find enough replacement monies to do all the things they have been doing under the current Grant. In all likelihood, some services will need to be curtailed. On the other hand, we believe that there are sufficient resources available elsewhere to allow continuation of those services which are deemed by the States to have the highest priority.

The $335 million which CAAs receive from the CSBG represents on average only 12% of their total budget. Roughly 85% of CAA budgets are supported by other Federal funding authorities.

- The General Accounting Office (GAO) reports and other studies indicate that CAAs use a range of from 30% to even 100% of their CSBG funds to supplement the administrative monies authorized by Congress for programs such as Head Start and the Low Income Home Energy Assistance Program. Other providers either find the administrative allowances adequate, or they are able to leverage additional administrative monies from non-federal sources. Effective CAAs surely ought to be able to emulate these successes were the CSBG to be terminated.

- Alternative sources of Federal funds to continue CSBG-funded direct services include the Social Services Block Grant (SSBG) and the Low Income Home Energy Assistance Block Grant (LIHEAP). The Department is proposing to amend the SSBG to make it completely clear that States will have the authority to use SSBG funds for virtually all of the kinds of services currently supported by the CSBG.

- States will continue to have the option of transferring up to 10% of LIHEAP funds to the SSBG to support a continuation of high-priority CSBG programs. In fiscal year 1984, 30 states transferred approximately $94 million from LIHEAP to five other block grants funded by the Department. In fiscal year 1987, up to $210 million will be available to the states for transfer.

  [In addition, states will have the authority to transfer to LIHEAP part or all of the $2.098 billion Exxon restitution fund which has just been distributed to the states. This should enhance the States' ability to transfer more money from LIHEAP to the SSBG to cover former CSBG activities deemed essential.]

- According to the 1986 Fiscal Survey of the States prepared by the National Governors' Association and the National Association of State Budget Officers, the State general fund year-end balances for fiscal year 1987 are projected to be $5.3 billion. Although the Survey notes that states "that project small ending balances are unlikely to pick up federal responsibilities", it also points out that "states that are generally better off financially have responded to the imminent federal cuts".

- Finally, CAAs can and should do more to leverage private sector resources. At the present time, cash and in-kind donations to the CAAs account for less than 2%, on average, of the total CAA budget. Yet the mobilization of such resources has, during the past twenty years, been one of the principal statutory objectives of the community action program.

Question. Are you concerned at all that the elimination of these funds will mean the elimination of services?

Answer. Yes, I am concerned about the elimination of some services to low-income people that could result from the elimination of the CSBG. But I am also concerned about the enormous deficits which threaten the ability of the federal government to meet its obligations. My concern is shared by the governors. In a survey of governors' priorities prepared by the National Governors' Association, the single federal-state issue cited as most important by governors and their staffs was the federal deficit. The survey notes that "Utah Governor Scott Matheson and Illinois Governor James Thompson, then NGA chairman and vice chairman, reflected the view of many governors in the spring of 1983 when they wrote in the Washington Post , 'Our nation's economic health cannot tolerate persistent annual deficits close to $200 billion'."

The size of the deficit makes it imperative that federal and state governments alike prioritize their needs and pare back those programs which are not absolutely essential. The best antipoverty program I can think of is one which is able to sustain, through further cuts in non-essential government spending, an economic recovery which to date has produced nearly ten million jobs without reigniting inflation, the chief threat

to individuals and families with low and relatively fixed incomes.

CHILDHOOD IMMUNIZATION

Question. Like much of OMB's budget this year, the proposed request for the childhood immunization program provides that States with certain options not unlike Sophie's Choice: either to purchase D-T-P (Diptheria-Tetanus-Pertussis) vaccines or to fund State operations of the vaccine program.

How much more would it cost to fund both the continued Federal share of the DTP vaccine purchases and State administration of the vaccine program?

Answer. The FY 1987 request for the Immunization grant program is $47.7 million; this includes $32.9 million for MMR and OPV vaccines, and $14.8 million for DTP vaccines and/or State program operations. Based on the proportion of these costs estimated to be supported by Federal grants in FY 1986, a total of $58.8 million would be needed to maintain these same proportions in FY 1987. Of this total, $32.9 million would be for MMR and OPV vaccines (the same as the current request), $17.2 million would be for DTP vaccines, and $8.8 million would be for State program operations, including the continuation of a rubella elimination initiative begun in 1985.

Question. I presume the budget assumes the States will make up the difference. Have you analyzed the ability of the States to make up the difference in both vaccine purchases and administration of the program?

Answer. We have not done an analysis of the ability of the States to make up the difference in both DTP vaccine purchases and program administration costs. However, we believe that the States, as partners with us in this effort, also recognize the importance of the immunization program and, where necessary, will seek to augment expenditures for State program administration costs and DTP vaccine purchases. The Federal government has only been providing funds for DTP vaccine purchases since 1985.

VACCINE STOCKPILE

Question. Mr. Secretary, this year's budget does not request any funds to maintain an adequate stockpile of vaccines in case of emergency or disaster at one of the few manufacturers of these vaccines. What is the purpose of the stockpile?

Answer. The vaccine stockpile is designed to provide an assured supply of vaccine in the event of short-term (6 months or less) problems with vaccine manufacturing, lot testing, or strikes which have generated supply problems in the past. While the stockpile could be used in the event of manufacturer withdrawal from production due to liability insurance concerns, it was not designed to be the answer to this greater threat to vaccine supplies. Once the stockpile supply was exhausted, it could not be replenished if no manufacturers remained in the vaccine market then because of the lack of liability insurance.

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Question. How close are we to the Department's previously stated goal of maintaining a 6-month stockpile of vaccines?

Answer. Funds have been appropriated through FY 1986 which will provide an aggregate 17-week supply of the major childhood vaccines in the stockpile, compared to the goal of a 6-month (26 week) supply. Individually, by vaccine, the following supplies are expected to have been accumulated by the end of FY 1986:

OPV - 20 weeks (78.3%)
DTP - 15 weeks (56.7%)
MMR - 15 weeks (56.7%)
Td - 18 weeks (69.8%)
DT - 15 weeks (59.0%)
IPV - 16 weeks (63.3%)

Contracts for these levels have been signed or will be signed during the year. Each contract calls for a phased delivery of vaccine to the stockpile, based on production capabilities and the need for normal vaccine deliveries to the public and private sectors.

Question. Isn't the stockpile a relatively inexpensive insurance policy against the threat of a sudden vaccine shortage?

Answer. A stockpile does provide an insurance for maintaining vaccine supplies during short-term interruptions. Having this backup reduces the risk that a backlog of unimmunized children would build-up in the case of a short-term interruption, and reduces the need for more costly and labor intensive recall programs for immunization when normal vaccine distribution was resumed. However, the costs of continued increments to the stockpile are no longer inexpensive, given the recent rapid increase in vaccine prices, such as the growth in DTP vaccines from 11¢ a dose in 1982 to $4.42 a dose estimated for 1986.

Also, the stockpile is not a substitute for dealing with the issue of the availability of affordable liability insurance, which is a greater threat to vaccine supplies today. Once the stockpile supply was exhausted, it could not be replenished if no manufacturers remained in the vaccine market then because of the lack of liability insurance.

Question. When are you planning to resume expansion of the vaccine stockpile? Are you more concerned about "the efficiency of Federal expenditures" (which are your words on p.34 of the justification) than you are about protecting our Nation's children against childhood diseases?

Answer. While bringing the stockpile up to an optimum 6-month supply remains a priority, several issues are now being considered in the area of vaccines that make it appropriate to delay further expansion of the stockpile for now. First, the Administration has transmitted legislation to the Congress to limit punitive and non-economic damage awards against vaccine manufacturers to help ensure

that these companies can obtain liability insurance. Second, new vaccines for DTP are being developed which are likely to replace the vaccines currently in use. Third, an additional manufacturer of OPV vaccine is expected to enter the market, and it is possible that a second company may be considering entering the MMR vaccine market. We expect that expansion of the stockpile could be resumed in the near future if these issues are resolved and funds become available.

Reprogramming of Computer Funds

Question: I understand there are excess funds in the Social Security Administration that will not be needed this year for computers. At the same time, I understand the Administration does not intend to keep the 1,000 staff added by Congress over the fiscal 1986 request, citing the 4.3 percent cutback imposed by the Gramm-Rudman legislation. Would you be agreeable to shifting excess computer funding to support staff costs--at least for 1,000 positions restored in the enacted fiscal 1986 Labor-HHS Appropriations Bill?

Answer: Although we requested deferral until FY 1987 of $114.6 million of the resources available for ADP/telecommunications activities in FY 1986, we would not recommend these funds be shifted to support the 1,000 positions that the Congress added to the Limitation on Administrative Expenses for FY 1986. While our current evaluation of 1986 projects and acquisition plans revealed that these no-year funds are not required during FY 1986, we do plan to use these funds in FY 1987.

Question: Why not utilize a portion of the $145 million contingency fund to carryout the intent of Congress that 1,000 Social Security staff be restored--which should cost no more than $30 million?

Answer: We will use a portion of the contingency reserve to add staff if otherwise service to the public would diminish. With continued evidence of improvements in service to the public, we believe it would not be a wise use of trust funds to hire and train additional staff at this time.

SUMMER UNEMPLOYMENT BENEFITS FOR HEAD START STAFF

Question. You are proposing that we add legislation in the appropriations bill to prohibit Head Start staff from receiving unemployment benefits in the summer months. Apart from the merits of this proposal, why don't you seek this in the authorizing legislation?

Answer. The Administration's legislative proposal for Head Start reauthorization will include language that prohibits between-term unemployment compensation.

Question. What would the impact of your proposal be in reducing the income of Head Start staff, many of whom are struggling to support their families while earning only the minimum wage?

Answer. According to the February, 1985 report on unemployment insurance cost issued by the Department of Health and Human Services, Office of Inspector General, the average amount of unemployment insurance collected during the summer by Head Start teachers was $1,210 while teacher aides collected $973.

Question. How much would have to be added to Head Start appropriation to offset the loss of these unemployment benefits?

Answer. ACYF estimates that 80% of Head Start employees not working in programs run by public schools systems are receiving between-term unemployment benefits and that the average amount collected per employee is $1,000. Head Start programs, according to the Inspector General report, each year contribute $15.6 million more than is minimally necessary to State unemployment funds because of the high incidence of unemployment benefit use. The $15.6 million would be saved if Head Start employees no longer received between-term unemployment benefits; however, the savings would not appear all at once, but over two or three years due to the lag in the way payments to the State unemployment fund are made.

We note, however, that offsetting the loss of these unemployment benefits would be inequitable because some Head Start employees are already prohibited from collecting between-term benefits. Offsets would also be inappropriate because funds would be distributed by forumla to States and would not necessarily compensate teachers currently receiving benefits.

Center for Nursing Research

Question. In 1985, Congress appropriated $5 million for the Center for Nursing Research, contingent upon an authorization. In 1986, the Center was authorized to be established at the National Institutes of Health. In the interim, to get the Center off the ground, your predecessor established a Center administratively within the Health Resources and Services Administration. The 1985 appropriation was extended into 1986 to allow sufficient time to authorize the Center.

Despite clear Congressional — and even Administration -- support for the Center, and despite serious evidence of need for nursing research funds according to a 1985 Institute of Medicine study, you are proposing to rescind the entire $5 million appropriated by Cngress to establish the Center at NIH. In addition, you are proposing no funding for the Center in 1987.

- Why are you opposed to the establishment of the Center for Nursing Research?

Answer. Our opposition to a separate line item for support of nursing research should not be viewed as an assessment by the Department that the kinds of studies and activities supported by the Center have been ineffective. Throughout the debates on the establishment of a Nursing Center the Administration has consistnetly opposed the establishment of a new administrative entity. The type of research which the Center has supported in the past should compete successfully for support from the National

Institutes of Health; Alcohol, Drug Abuse, and Mental Health Administration; and National Center of Health Services Research.

MEDICAID GROWTH LIMIT

Question. The budget proposes "savings" of $1.0 billion by cutting Federal payments below current spending projections for FY 1987. Funds would be distributed to States based on each State's relative share of FY 1985 spending. Future increases would be indexed. However, the Department projects that under current law, the rate of growth in Medicaid expenditures will be 8% per year from 1987-1991. How can the States afford to continue quality care to a 3 percent caseload increase with funding that will be reduced by 5 percent?

Answer. In these times of high budget deficits, it is not unusual for States, and Federal agencies for that matter, to be asked to continue to perform many functions with reduced funding. In both Medicare and Medicaid, the Department's budget contains incentives to improve the efficiency of health care delivery. The Department believes that improved efficiency can be obtained without sacrificing quality care.

While the States would face a Medicaid budget reduction of $1.0 billion below the current services funding level under the Department's budget, States would be granted increased flexibility in program design and provider reimbursement in order to achieve the necessary savings.

The States would not face a budget reduction of 5 percent, rather their Medicaid expenditures would not grow as fast under the Department's FY 1987 budget as they otherwise might have.

Question. You further state that legislative proposals to AFDC will produce an additional $284 million savings to Medicaid to assist the States. Given that Congress hasn't enacted these proposals in the past and given that this is the Appropriations committee and not the authorizing committee, aren't these additional "savings" false assumptions?

Answer. While it is certainly true that the Congress has not enacted similar proposals submitted in previous Administration budgets, the arguments in favor of the FY 1987 budget are even more compelling in the Gramm-Rudman-Hollings era.

The AFDC proposals make programmatic sense and the Administration is optimistic about their changes for passage.

Question. You state that "a number of measures will be proposed to assist States in meeting the ceiling." What types of measures do you mean?

Answer. States would be given increased flexibility in a number of areas to achieve the budget savings.

States would be given increased flexibility to design their benefit packages for all recipients other than the mandatory

categorically needy. States would be able to tailor benefit packages for specific eligibility groups, thereby better targeting their Medicaid dollars.

Federal requirements for "statewideness" and "freedom of choice" would be retained only for mandatory services to mandatory groups; States could assess nominal copayments on mandatory services for mandatory groups, and other restrictions on copayments would be eliminated; and all minimum requirements concerning provider reimbursement rates would be repealed.

States would be able to apply the savings from the second surgical opinion program, the prescription drug reform proposal, and the AFDC reforms to the Medicaid cap.

By utilizing all of these proposals, States could reform their Medicaid programs to meet the budget savings requirements.

MEDICARE COST CONTAINMENT

Question. Mr. Secretary, your budget proposes continued tightening up on payment to providers -- hospitals and continuedphysicians. Included in these proposals are (1) the inclusion of hospital capital costs in the Prospective Payment System (PPS) and (2) continued adjustments to physician payments. At what point do you determine that cost squeezing is having an impact on the quality of care? Do you think providers will ultimately pass on the costs to the consumer in the form of additional fees?

Answer. Together our proposals for 1987 will provide a slight increase in overall hospital payments. Given reports from the hospital industry and the General Accounting Office of increased hospital profitability under PPS, we do not believe that the payment levels proposed will lead to reductions in quality. In fact, although we have heard anecdotal reports, we have no evidence that there is a system-wide quality problem.

In addition, the Peer Review Organizations will continue to assure that only medically necessary, high quality hospital care is provided to Medicare beneficiaries. To further assure that care meets quality standards, we have expanded the PRO contractual scope of work for the coming contract period to include reviews done through generic quality screens. We will also have PROs review all readmissions to hospitals within a 15 day period following discharge, rather than the current 7 day period. These efforts are expected to better ensure quality of care.

Similarly, a projected increase in outlays for Medicare physician payments in 1986 of over 12 percent along with industry reports that physician incomes increased in 1984 an average of 7 percent, lead us to believe that physicians are not being forced to compromise on the quality of services. Even with enactment of all our FY 1987 physician payment reforms, expenditures are expected to increase almost 7 percent. Without our proposed reforms, physician payments will

increase over 11 percent, an increase that is not consistent with our efforts to reduce the federal deficit.

Overall, we believe our FY 1987 budget proposes thoughtful limits on increasing cost, that can be accomplished without having a negative impact on the quality of care provided to beneficiaries.

ESRD NETWORK COUNCILS

Question. Mr. Secretary, your budget proposes to reduce the number of End Stage Renal Disease Network organizations from the current 32 to 2. I have received letters from all over the country requesting the continuation of this program. The letters have come from recipients and providers. Why does the Administration continue to propose elimination of this program when the Congress continues to restore funding?

Answer. We believe that the Network Coordinating Councils have not been successful in accomplishing their legislative or regulatory functions.

Current regulations require the networks and medical review boards to develop criteria to evaluate the quality of care provided in the facilities. Many of the existing network organizations have failed to develop and adopt measurable criteria that evaluate the quality of appropriateness of care; instead they focus on factors that define utilization of ESRD services. (For example, duplicative review of patient care plans.) Rather than evaluating and improving the procedures used in placing patients for treatment, the present organizations have tended to review requirements contained in the regulations on the conditions for coverage, thus duplicating the efforts of State survey agencies.

The 32 current networks vary in geographic size, facility membership, and number of patients. An emphasis on data collection and verification have resulted in the networks focusing less attention on quality assurance initiatives. Funding for the existing network organizations, including the network coordinating councils and medical review boards, is provided through grants. For calendar year 1984, 88 percent of the networks' total funding was used to meet fixed costs (for example, salaries and fringe benefits, office rental, supplies.) This has resulted in only minimal resources being available to address quality assurance activities. While we recognize that some of these fixed costs are necessary and contribute to an organization's ability to meet its objectives, maintaining the 32 current network organizations consumes available resources unproductively. Furthermore, among the existing networks, there are substantial and unjustified variations in the quality of performance and in the cost effectiveness of the different networks in meeting their statutory responsibilities.

When the existing networks were established, health planning agencies and Professional Standards Review Organizations (PSROs) were not fully operational and were not equipped to

address the issues concerning ESRD treatment resources. We believed that networks should contribute to assuring an adequate and equitable growth of costly and scarce resources and help to assure access to quality care in the appropriate treatment modality. However, the existing network organizations proved unequal to the task of evaluating and planning for the growth of ESRD services. Since the large majority of network members were facility representatives, there was considerable potential for conflicts of interest in the planning process, and we received numerous complaints about this role of the networks. To alleviate this problem, we removed the existing network organization from the active role in the planning process and limited them to providing patient demographic data to the authorized planning agencies. The health care delivery system generally is capable of accomplishing operational coordination of the delivery of needed services through market and other mechanisms (prospective payment) without reliance on special additional organizations such as ESRD networks.

Finally, while there has been an increase in home dialysis and transplantation rates, we believe that these improvements in patient rehabilitation generally are a result of technological advances (for example, continuous ambulatory peritoneal dialysis and cyclosporine therapy), proliferation of treatment resources and the implementation of the prospective reimbursement mechanism that provides incentives for treatment in less intensive settings, rather than as a result of the efforts of existing network organizations.

Question. What are your plans for the Networks for FY 1986?

Answer. We plan to issue a regulation giving us the authority to reduce the number of networks. We propose to consolidate the ESRD networks to the smallest practicable number and establish new, more efficient network organizations funded on a competitive basis.

Question. If your plans include eliminating networks in FY 1986, will you submit a reprogramming request to accomplish this? When would you do that?

Answer. The ESRD Network Coordinating Councils are currently funded on a calendar year basis. Therefore, if our FY 1987 legislative proposal to eliminate the ESRD Network Coordinating Councils is enacted, we would commence the phaseout of Councils in the Fall of 1986. We do not believe that this phaseout, if mandated by law, would require a reprogramming of funds in FY 1986.

We are currently reviewing the possibility of a reprogramming request in conjunction with our plan under current law to reduce the number of ESRD Networks and Network Coordinating Councils. However, finalization of our plan on the consolidation is contingent upon whether the Consolidated Omnibus Reconciliation Act of 1985, currently being considered by Congress, is signed into law. Since this proposal may

affect our plan, we cannot at the present time specify in more detail the nature and timing of a possible reprogramming request.

VACCINE PRODUCTION

Question. How many producers of polio vaccines are there at present?

Answer. One company is licensed to produce OPV vaccine for the U.S. market.

Question. How many manufacturers of measles-mumps-rubella vaccines are there presently?

Answer. One company is presently licensed to make MMR vaccine for the U.S. market.

Question. How many rubella?

Answer. One company is licensed to make rubella vaccine (same as #2 above).

Question. What are your plans to stimulate more companies to get into the vaccine business?

Answer. As indicated above, several new sources of some of the childhood vaccines may be considering the market. In today's climate, it is difficult to stimulate new entries in the market for certain childhood vaccines where litigation and product liability costs are high. This is particularly true for current DTP used in the U.S. We are working with the manufacturers, however, to develop new, less reactogenic vaccines and to document their efficacy so that U.S. licenses can be granted by the FDA.

However, the greatest threat to the supply of vaccines remains the liability issue. The Administration transmitted legislation to the Congress last year to ban punitive and limit non-economic awards against vaccine manufacturers. We believe that this legislation would greatly reduce the threat of vaccine manufacturers leaving the market, and could encourage other manufacturers to enter the market. This could not only reduce the probability of vaccine shortages but also help contain the increasing cost of vaccines.

Questions Submitted by Senator Warren Rudman

TRI-STATE CONTRACT

Question. What does HHS and HCFA see as the problem with the Medicare "B" contractor performance in the Three-State contract to date?

Answer. The problems initially experienced by the Tri-State contractor have resulted from a lack of sufficient

staffing to handle the volume of claims received and phone lines to handle beneficiary inquiries. The staffing situation caused claims and appeals activity to backlog as well as beneficiary toll-free lines to exceed prescribed busy signal levels.

Question. What has HCFA done to make certain the contractor is correcting the problems? What is the status of any corrective action plan? How long will it take?

Answer. The problems became evident in mid-December. HCFA requested that a corrective action plan be submitted in early January. The Regional Office set up a task force to work closely with Blue Shield of Massachusetts to carry out the corrective action plan quickly and permanently.

The corrective action plan goals are expected to be reached by the end of March. Workload goals for appeals and responding to correspondence were exceeded by March 1. The contractor is expected to meet the claims pending goal by the end of March. We are continuing to closely monitor performance in these problem areas. Telephone service has improved dramatically since December. Two additional phone lines were installed on March 10 and are expected to reduce the busy signals to prescribed levels. The task force will retest the phone service beginning March 17 and intermittently thereafter.

Question. Once the inventory of old claims and appeals is down to normal levels, what assurance can Blue Shield of Massachusetts give you that the necessary changes have been made to prevent the problem from reoccuring in the future?

Answer. Blue Shield of Massachusetts does not expect the inventory and phone service problems to recur because 18 additional staff have been hired and trained in the claims, correspondence, review and phone service sections. Changes have also been made in the management staff at the Tri-State processing plant in Biddeford, Maine. We believe that Blue Shield of Massachusetts high level management is committed to maintaining improved levels of service for the Tri-State contract.

HCFA will continue to monitor staffing levels and performance intermittently over the life of contract to assure compliance with standards for service to Tri-State beneficiaries.

Question. Are there some systemic problems beyond inadequate staffing and jammed telephone lines? Does the contractor have the necessary state-of-the-art data processing system to solve problems such as the batching of 400 individual checks in payment of 400 individual claims to one provider?

Answer. We believe there is no systemic problem with the Tri-State contract. Blue Shield of Massachusetts has a state-of-the-art processing system which can be tailored to solve problems like those stated. This system has been used for Medicare claims processing in the state of Massachusetts since

1984 as well as at other Medicare contractors throughout the United States.

Question. If this contractor's performance does not improve to an acceptable level by this Summer, would HCFA consider yanking the contract for failure to perform and put it back out to bid?

Answer. The contractor's performance has substantially improved. The first complete contract assessment will be conducted beginning in July, 1986. Incentives or damages will be applied on the basis of those assessment results, probably in October.

If overall performance is clearly deficient, HCFA has a number of options available: work with the contractor to correct problems, reduce the size of the territory, select a replacement contractor, or conduct a competition to select a replacement. If performance deteriorates, we will take action as appropriate.

Question. Are there any circumstances where HCFA would simply renegotiate Massachusetts Blue Shield Medicare "B" contract price? If there are such circumstances, would not HHS and HCFA be rewarding "low-balling" and, provide incentives for contractors to intentionally underbid contracts destroying the intent of the fixed price competitive contract bidding?

Answer. There are no circumstances under which HCFA would simply renegotiate a fixed price contract. If the bid price is accepted, contractors are held to that price. Additional amounts are paid only for additional work that was not contemplated in the original contract price. Sufficient documentation must be submitted before such payments are made.

Question. Why did HCFA, when the Deficit Reduction Act of 1984 clearly stated congressional intent to weed out poor performing contractors, take Medicare "B" contracts in New Hampshire and Vermont away from the number two ranked contractor in the country (NH Blue Cross/Blue Shield) and award it to one of the poorest performing contractors in the country (Massachusetts Blue Shield), which by your own ranking is currently among the lowest 20 percent in contract performance?

Answer. The Maine, New Hampshire, Vermont competition was conducted under our fixed price experimental contract authority. The incumbent fixed price contract in Maine was ending in October 1985 and a choice had to be made on what to do at the end of that experiment. There were three options: revert to a cost contract, recompete Maine only or expand the competition to include additional territory. Because no experimental premise would be tested by recompeting Maine for a second time, we chose to hold a three State competition. The carrier servicing New Hampshire and Vermont was performing well and bid on the Tri-State contracts. At the time (May, 1985) of the competition, Blue Shield of Massachusetts was also performing in an acceptable range above average. With the evaluation based equally on cost and performance, Massachusetts Blue Shield was awarded the contract.

It is true that Massachusetts Blue Shield appears on the bottom twentieth percentile list developed in December, 1986. However, this list was developed well after the competition was held. We are working closely with Massachusetts Blue Shield to improve their performance in FY 86.

Question. With current budgetary constraints is HCFA forced to put the priority on program costs at the expense of service? If so, how can the integrity of the Medicare program be maintained? How much more budget authority would HCFA need to assure an acceptable level of service?

Answer. We believe that our contractor budget allows for protection of program dollars while maintaining a high level of service to our beneficiaries. Whenever problem areas develop they are immediately addressed by HCFA. This has been the case with the Tri-State contract. No additional budget authority is needed to maintain quality service.

Questions Submitted by Senator Arlen Specter

Black and Minority Health Gap

Question: On October 16, 1985 former HHS Secretary Margaret M. Heckler announced the establishment of a new office within the Public Health Service to supervise Federal efforts to improve the health of members of minority groups. She committed $3 million in FY 86 to support this effort.

This commitment was the result of a year-long study commissioned by former Secretary Heckler which showed an alarming disparity in the health status of whites and members of minority groups. According to the Secretary's Task Force on Black and Minority Health, Black, Hispanic and Native American people "have not benefited fully or equitably from the fruits" of biomedical research. Further, approximately 60,000 deaths could be avoided each year if mortality rate for Blacks and members of other minority groups were on a par with non Hispanic whites.

Secretary Bowen, the budget which you have submitted does not indicate that you plan to follow through on the commitment to provide $3 million to establish an office to supervise Federal efforts to improve the health of minorities. What steps, if any, have you taken to follow through on an Office of Minority Health, what is the funding available to this effort in FY 86 and FY 87? How have you ensured that this office will have "teeth" within the Department of Health and Human Services?

Answer: The Office of Minority Health was officially established in the Public Health Service by notification in the Federal Register and Dr. Herbert Nickens was appointed director of the new Office. The Office will be responsible for monitoring the implementation of the recommendations of the Task Force on Black and Minority Health.

Approximately $3 million will be allocated to the Director of the Office of Minority Health from agencies throughout PHS.

In order that this Office will have sufficient access to needed resources at the appropriate level, the director will report directly to the Assistant Secretary for Health. This will help to ensure success in his efforts to come up with a workable approach toward improving the health of blacks and minorities.

REDUCING LOW BIRTHWEIGHT BABIES AND INFANT MORTALITY

Question. Mr. Secretary, on November 21, 1985, I introduced S. 1873, the Community Based Disease Prevention and Health Promotion Projects Act. This legislation authorizes $15 million for the development and implementation of community based health education and outreach efforts targeted to women who are high risk for having low birthweight babies--a major cause of infant mortality. My bill targets efforts towards minority women, teenage girls and poor women. These women often receive late or no prenatal care, and may have lifestyles--poor nutrition, smoking, alcohol or drug use--which endanger the health and life of the expected child.

A 1985 report from the Children's Defense Fund entitled Black and White Children in America indicates that 61.5 percent of Black women begin prenatal care in the first trimester as opposed to 79.3 percent of white women. Furthermore, 3.1 percent of Black women receive no prenatal care, but only 1.2 percent of white women receive no prenatal care.

Mr. Secretary, I note that you have sought a rescission of $21 million in the Community Health Centers budget. Rather than requesting a rescission, why are you not targeting these funds for community based health education and outreach efforts so that we can reach the 39.5 percent of Black women who are not beginning prenatal care in the first trimester, and the 20.7 percent of white women who are not obtaining prenatal care in the first trimester? Wouldn't this aid in our effort to reduce the number of low birthweight babies and infant mortality?

Answer. The development of the Federal Government's budget is a process during which decisions have to be made regarding putting limits on every Federal program, even the most worthy. In the context of the resources available, it was determined that $375 million would be sufficient to provide a basic level of services. That does not mean that if more resources were available some increment of benefit could not be achieved through increased funding for Community Health Centers. But this same statement could be made concerning a multitude of Federal programs.

PROFESSIONAL LIABILITY AND ACCESS TO HEALTH CARE

Question. The issue of professional liability is raising some concern about whether certain segments of the population, particularly pregnant women, will be denied access to health care. In February, for example, in Boston, at least 250 physicians, most of them in high risk specialties refused to perform surgery or take on new patients in protest against rising malpractice insurance rates.

In Kent County, Maryland, obstetricians in private practice are no longer accepting Medicaid patients or women who they fear will not pay their bills. These women must go to a public health clinic for prenatal care and then carry their medical charges to a hospital emergency room when it is time to deliver their babies.

In Kansas, more than 30 percent of the obstetricians and family practitioners who provided obstetrical care have stopped delivering babies. According to the American College of Obstetricians and Gynecologists, 12 percent or 1,400 of their members surveyed in 1985 had dropped obstetrics because of the risk of malpractice.

In Pennsylvania, obstetricians in the Philadelphia, Delaware and Montgomery County areas pay about $40,000 for insurance--almost double the rate paid in the rural areas of the state.

Secretary Bowen, how can the Department of Health and Human Services help ensure that pregnant women, Medicaid recipients,and others in need of health care are not left without access to care, in the fact of the increasing number of physicians in high risk specialties who are abandoning the specialty, or are refusing to take on new patients? Have you reviewed the situation in Kansas, Maryland, and other parts of the country where poor and pregnant women are having difficulty getting care?

Answer. We have not specifically reviewed the situation in Kansas and Maryland; however, medical liability, defensive medicine, and malpractice insurance all go together and are having serious impacts on health care in this country. When I was Governor of Indiana, we passed what I consider to be a model State law back in 1975. It was fairly simple. We put a limit on the time in which a suit could be brought. We established a panel chosen by both sides to make a determination whether it was truly malpractice or whether it was a nuisance type suit. Finally attorney charges were negotiated for the first $100,000 of settlement, but there was a 15 percent limit on everything above $100,000.

In regard to the situations which exist in Maryland and Kansas, we certainly are available to provide such professional consultation and technical assistance as may help alleviate the problem. Federal financial resources are made available to States either through entitlement programs, or in the form of Block Grants such as the Maternal and Child Health allocation. Each State is afforded considerable latitude - especially under the Block Grant Authority - to utilize the funds according to its own perception of priorities and needs. While the Department seeks to assist in the several ways described, ultimately, the States and communities must determine which needs and activities are of the highest priority in the context of the various demands placed on current resources and make resource allocations accordingly.

Questions Submitted by Senator William Proxmire

Prenatal Care

Question: Secretary Bowen, am I correct in assuming that the Department continues to be concerned about the problem of low birthweight babies?

Answer: Low birthweight babies are a major factor associated with neonatal and infant mortality, and is associated with maternal health behaviors during pregnancy, such as use of cigarettes, alcohol abuse, and poor nutritional practices. Cessation of health risk behaviors can have a positive effect on birth outcome and the Department is very concerned and involved in getting this message out to young mothers and mothers-to-be.

Question: As you know, inadequate prenatal care is a major factor in the equation producing low birthweight babies. Last year's Committee report includes language directing the Department to explore the extent to which States and localities are failing to provide prenatal care to low-income women because prospective clients are not told of their eligibility for such care when they become pregnant, pregnant undocumented aliens are unwilling to risk identification, and so forth.

A report to the Committee on the extent of the problem and steps that can be taken to improve the delivery of prenatal care was due on January 1. The report has not been received. Can you tell us where you now stand on the problem?

Answer: The Health Care Financing Administration is preparing this report and will be consulting with State Medicaid agencies about the delivery of care to low income prenant women. There were some initial misunderstandings as to which agency was assigned to prepare the report. This has been classified and we anticipate a finished product in 6 to 8 weeks.

INDIRECT COSTS

Question. An issue that will receive a substantial amount of attention over the next few months is indirect costs. As you know, the Administration is proposing a 26-percent-of-direct-costs cap on the administrative component of indirect research costs effective April 1, 1986, with a cut to 20 percent effective April 1, 1987.

I have been particularly concerned over the failure of indirect costs to be considered as a part of each NIH research proposal. They are computed after the fact and, until I inserted language in a Committee report a few years ago mandating their disclosure, were not even included in individual grant award announcements.

A panel of 13 industry and academic leaders recently came out with a report on indirect costs which, among other things, recommended that all Federal agencies adopt the National Science Foundation practice of including indirect costs in the project budget subject to review.

Do you agree with this recommendation and, if so, when will it be implemented by NIH?

Answer. The NIH is currently reformulating the standard PHS grant application form so that, among other things, it will display the full costs being requested. Under the terms of the Paperwork Reduction Act, this proposed change to the application form will require OMB approval before it can be implemented.

Through this approach of displaying full costs, peer reviewers would have the opportunity to know the requested reimbursement for indirect costs and to comment on any apparent anomalies. However, peer review groups will not be empowered to effect changes directly or arbitrarily in the amounts requested for reimbursement of indirect costs. As always, final decisions affecting indirect costs will be made by those having the relevant expertise. Specifically, officials in the regional offices of the Department of Health and Human Services will establish indirect cost rates, and staff of the National Institutes of Health will check each application to ensure that the rate is cited and applied correctly.

NSF FUNDING

Question. Mr. Secretary, the Administration is proposing a cut of about 8 percent in the fiscal year 1986 pre Gramm-Rudman-Hollings NIH budget — a cut of about 3.7 percent in the 1986 budget minus sequestered funds.

On the other hand I understand that the National Science Foundation's budget would increase by 8 percent under the President's proposals with the NSF's Biological, Behavioral and Social Sciences Directorate receiving a 9-percent increase.

As one of the participants in the budget formulation process, can you give us any insights into why the NSF budget is going up while the NIH budget goes down?

Answer. I believe the merits of the proposed budget increases in other research and development programs are best left to the determination of the Administration and Congress following analysis and debate of the many issues involved. As the Secretary for the Department of Health and Human Services, I can only speak to the merits of the research NIH supports and the very excellent opportunities that exist for expanding our knowledge of the processes that underlie disease and mortality.

The NIH budget of $4.9 million is an amount we believe is appropriate to maintain a viable research program in FY 1987.

NIH REVIEWS

Question. Secretary Bowen, I found a comment on page 7 of your prepared opening statement rather intriguing. You state, and I quote, "NIH will devote greater cost consciousness in the review and funding of project proposals." Does this mean that NIH will require grantees to absorb more of the costs of doing individual research projects, or be more selective in determining which proposals are funded, or both?

Answer. All project proposals are currently reviewed carefully for scientific merit and for appropriateness of budget. Our peer review groups are knowledgable about the cost of research and the facilities available at the institutions submitting the requests. Furthermore, these groups spend considerable time reviewing the requests. The intention of the quoted statement is that we will redouble our efforts in this area. Staff will have greater input, as will the peer review groups and Councils, to assure budgets are appropriate. The awarding BID staff will also review applications carefully before awards are made so that costs can be reduced wherever possible. We do not intend to have grantee institutions absorb an inappropriate share of the expenses of doing research, nor do we intend to rule out important research because it is expensive. Our intent is to assure that the funds allocated are even more carefully scrutinized than is now the case.

OTA REPORT ON USE OF ANIMALS IN RESEARCH AND TESTING

Question. A report issued last month by the Office of Technology Assessment regarding the use of animals in research and testing indicates that not all of the Department's animal facilities are accredited by the American Association for Accreditation of Laboratory Animal Care. Can you tell us why?

Answer. Accreditation of all intramural NIH animal facilities is a goal that was established by the NIH Board of Scientific Directors in 1977. Eighty percent of NIH intramural animal facilities are accredited by AAALAC; the remaining 20 percent represent largely scattered decentralized animal holding areas often shared by more than one Institute. Many of these intramural facilities were constructed in the 1940s and 1950s and were considered at that time to be "state of the art," but some facilities have not been sufficiently upgraded in the interim to meet accreditation standards. In August 1985 the Director of NIH established a goal that all NIH intramural facilities should meet accreditation standards by early in FY 1988, and this matter is of highest priority.

Question. How much would it cost to bring all of HHS' animal facilities up to AAALAC's standards?

Answer. The estimated minimum cost of renovation and construction of NIH intramural animal holding facilities is approximately $13 million. This figure does not include the cost of renovating laboratories that would be relocated as a result of renovation and construction of animal holding facilities.

Schizophrenia Research

Question: Mr. Secretary, on page 8 of your opening statement you indiated that the Alcohol, Drug Abuse and Mental Health Administration will place emphasis on addressing the major problem areas of shizophrenia and depression. However, your extramural research budget for these programs would fall from $36,954,000 in 1986 to $34,606,000 in 1987, a cut of 6.4 percent.

Childhood disorders, to take an example, would be cut by

only 2.7 percent while mental disorders of aging would also be sliced by just 2.7 percent.

Why do you place such an emphasis on research into schizophrenia and depression in your prepared statement when that research is taking a deeper cut than other programs you don't even mention?

Answer: The issue can best be understood by separating the schizophrenia and depression budgets. The extramural program in schizophrenia research will remain constant from 1986 to 1987. The total schizophrenia research program, however, including our intramural efforts will remain level at $21 million — as are the total reesearch programs for children and the elderly.

On the other hand, the budget for depression will decrease by 8.8 percent. This does not reflect a decrease in the level of effort; rather, it marks the end of one phase of our work and the start of a new and somewhat less expensive segment. For many years, we have invested in a variety of intensive and costly basic research enterprises, designed to build our base of knowledge about depression. Some of these projects are now winding down and have produced the sort of information which we sought. Our next objective — and this is what was referred to in my opening statement -- is to use this information to increase public awareness and to improve the capacity of professionals to recognize and treat depression. This effort will not be supported solely with Federal funds. We will attempt to force a public and private partnership that would link our scientific leadership and expertise with the resources of the public and private sector. The general goal of this effort is to improve the early identification and treatment of depression.

Donations and support from the non-Federal seector will account for a major share of the expense of our Depression Awareness, Recognition and Treatment (DART) program. It is for this reason that our budget shows some offsetting decrease in Federal support for this effort in 1987.

Service to the Public

Question: Mr. Secretary, on page 20 of your prepared statement you say: "To date, software and systems upgrades have reduced processing time and error rates, and improved SSA's service to the public."

Could you tell us how many hours or days have been cut from the Social Security Administration's processing times over the past year?

Answer: The Social Security Administration has reduced the National mean of claims processing time from the quarter ending September 1984 to the quarter ending September 1985 as follows:

— Retirement and survivors claims from 23.4 days to 21.4 days,
— Disability claims from 70.7 days to 66.0 days,
— Supplemental Security Income aged claims from 16.3 days to 10.8 days,
— Supplemental Security Income blind and disabled claims from 71.4 days to 57.7 days.

Error Rates

Question: How about error rates? How has the error rate percentage changed over the last 12 months?

Answer: Over the last 12 months the accuracy rate has remained at a level rate of 99.5 percent for RSI and 96.7 percent for SSI.

Advancement of Women and Minorities

Question: Secretary Bowen, for some time now I have been concerned over the under-representation of women and minorities in higher level jobs -- those at the GS-12 and above level.

For example, although women represented 64.1 percent of the HHS workforce in calendar 1984, they held only 35.7 percent of the GS-12 to GS-15 jobs and a mere 15.2 percent of the Senior Executive Service (SES) and executive level jobs.

Did the situation improve in calendar 1985?

Answer: The following table compares the percentage of somen in jobs at thheGS-12 level and above. These figures, obtained from the HHS automated personnel data system, are end-of-year 1984 a.d 1984 percentages taken from the data base that includes all active employment (i.e., permanent, part-time, temporary, etc.). One can see that the trend is up in both categories:

Women in HHS

	Dec. 1984	Dec. 1985	Change
GS/GM 12-15.....	31.5%	32.6%	+1.1%
SES/Executive.....	15.4%	16.0%	+0.6%

When assessing whether any group is represented in the work force, it is important that the proper basis for comparison be provided. In the grades GS-12 and above most HHS employees are in professional administrative occupations and their numbers should be compared to the numbers of people in the U.S. labor force who have the training, skills, and experience to qualify for professional/administrative positions.

Equal Employement Opportunity Commission (EEOC) data from

the 1980 census report establishes the following U.S. labor force guidelines:

Women in professional occupations	32.1%
Women in administrative occupations	31.7%

While the Department still has work to do, the trend is in the right direction.

Question: In calendar 1984 blacks constituted 24.2 percent of the HHS workforce yet held only 13.5 percent of the GS-12 to GS-15 jobs and 7.2 percent of thh SES/Executive Level jobs.

Can you give us the percentages for calendar 1985?

Answer: For calendar year 1985 blacks made up the following percentages of the workforce in jobs at thee GS-12 level and above.

	Dec. 1984	Dec. 1985	Change
GS/GM 12-15.....	12.2%	12.3%	+0.1%
SES/Executive.....	7.2%	7.7%	+0.5%

When these percentages are compared with the EEOC guidelines, it can be seen that HHS has done very well in the employment of black in the GS/GM 12-15 grades and in the SES/Executive levels.

Equal Employement Opportunity Commission (EEOC) data from the 1980 census report establishes the following U.S. labor force guidelines:

Blacks in professional occupations	5.1%
Blacks in administrative occupations	6.7%

Questions Submitted by Senator Lawton Chiles

LOW BIRTH WEIGHT INITIATIVE

Question. I see a rescission request for the National Institute of Child Health. Coupled with the Gramm-Rudman cuts, it would bring the $321 million we provided in 1986 down to only $309 million in 1987. Last year Dr. Wyngaarden testified on the clinical trials and studies on low birth weight, plans for a network of maternal fetal medicine units for high risk mothers. What effect will the President's budget have on these efforts?

Answer. The National Institute of Child Health and Human Development anticipates spending $38.8 million in FY 1987 in the area of low birth weight and infant mortality, an increase of $1.0 million over the FY 1986 revised level. In FY 1987 the Institute will continue to fund seven units in each of two networks established in FY 1986: maternal/fetal medicine and neonatal intensive care. In these networks, early stage clinical trials will focus on such issues as prevention and management of premature rupture of the

membranes, management of premature labor, testing the effectiveness of an ambulatory tocodynamometer device worn by the pregnant woman to detect uterine contractions of premature labor and allow intervention to stop the contractions and prevent premature delivery, and development of better nutritional support for the very low birth weight infant. The proposed 1987 budget will permit funding one or two clinical trials in each network.

Medicaid Coverage of High-Risk Pregnant Women

Question: The Southern Governors Assocation task force on infant mortality has made some recommendations on how Medicaid should be expanded to reach pregnant women and children in the high risk groups. I understand you are doing some cost studies on their proposals, and I want to commend you for that.

What is the status of your cost analysis of these proposals? I would hope we could get something soon.

As you look at the cost, are you also analyzing the benefits? We know, for instance, that prenatal care costs about $600, while neonatal intensive care can cost up to $120,000-$200,000. One dollar spent on WIC has saved up to $3 in short-term hospital costs. A dollar investment in Medicaid prenatal services can save $2 in the infant's first year of life. Are you doing a cost-benefit analysis?

Answer: The Department of Health and Human Services has a continuing interest in the availability and delivery of Medicaid services, and in associated costs and opportunities for efficiencies (i.e., cost-benefit analysis). It is in this context that we regularly integrate and analyze complex program data and supplementary information including, of course, that related to infant and maternal and child health. Although we are not specifically costing-out the Southern Governors Association's concepts per se, we expect that some components of the Department's analyses will be useful to the Association in their deliberations. These analyses are likely to be completed later this year.

INFANT MORTALITY

Question. Given what we know about the risk factors for low birthweight and infant mortality--unmarried mothers in their teens, smoking, drinking, drug use, and failure to get early prenatal care and good nutrition--shouldn't there be a concerted effort within the Department to coordinate a united message to the public. You've got the Maternal and Child Health Block Grant, the anti-smoking campaign, drug and alcohol abuse programs, adolescent pregnancy and family planning programs. Shouldn't this be coordinated to reach pregnant women and potential mothers?

Answer. The Healthy Mothers, Healthy Babies Coalition responds very directly to these concerns. The Surgeon General's Workshop on Maternal and Infant Health in December 1980 set the stage for action to improve infant health. Recommendation 33 from the Surgeon General's Workshop stated: "The Workshop urges the Surgeon General to use the influence of his office to develop a strategy of public

information and education to promote the recognition of the great value to the Nation of healthy pregnant women and infants." Subsequently, the Public Health Service and the March of Dimes asked the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, the Parent Teachers Association, and the American Nurses Association to join them in a planning meeting. Representatives of these six organizations met in White Plains, New York, on June 23, 1981. In White Plains, a statement of purpose was drafted and the six participants agreed to co-sponsor an organizing meeting.

That evening in Indianapolis at the March of Dimes Annual Recognition dinner, Health and Human Services Secretary Richard S. Schweiker announced the launching of a campaign to teach women how to reduce the chances of health problems for their babies by practicing preventive health care. The Secretary said, in part; "We are tremendously encouraged by the fact that . . . . national voluntary organizations are taking part because with the participation of community-based groups, we can successfully reach a wide audience of American women."

The Organizational Conference was held on September 23, 1981. Representatives of more than 36 national voluntary, professional, and governmental organizations met to discuss methods of collaborating. Out of this meeting grew the Health Mothers/Health Babies Coalition. At the second national meeting in 1983, the Coalition had grown to more than 60 members and in 1985 had more than 70 member organizations.

The National Healthy Mothers/Healthy Babies Coalition has supported the development of over 40 State Healthy Mothers/Healthy Babies Coalition, and in some States, sub-State Coalitions are developing. The effort has increased public and provider awareness of the need for early and appropriate prenatal and infant care, has prepared and disseminated informational materials for print, radio and TV, and has enhanced sharing of information and materials among participating organizations and their individual members. The Coalition functions through a system of interlocking Sub-Committees and a small Secretariat.

Question. The Infant Mortality Task Force of the Southern Governors Association has recommended that the Office of Maternal and Child Health should be designated the lead agency on infant mortality and coordinate this effort. What do you think about this recommendation?

Answer. The Assistant Secretary for Health (ASH) has established a Low Birth Weight Prevention Work Group which is co-chaired by the Director of the Division of Maternal and Child Health (DMCH) and the Director of the National Institute for Child Health and Human Development. The activities of this group, which represents all major department components concerned with infant mortality, provide the level of coordination which is required at this time. Because of its appointment by the ASH, any problems of interagency cooperation could readily be resolved through access to the ASH. We believe this is an approach preferable to the DMCH designation because of the close ASH connection and because the work group is co-chaired by the DMCH Director and therefore,

automatically incorporates his Division's full resources and involvement.

Question. Last fall the Governmental Affairs Committee held a hearing at Providence Hospital in D.C. on a bill I have introduced to create a National Commission on Infant Mortality. Dr. Mason of your Department testified that teams of experts would be available for the States that want technical assistance on reducing infant mortality. Yet there did not seem to be any systematic plan for getting these teams out to the States or any real investment in resources in the effort. In fact, only three States had had visits.

Do you plan to continue this initiative?

Answer. Infant Mortality Review continues as an area of major effort within the Public Health Service (PHS) and encompasses a broad range of alternatives aimed at reducing infant mortality and low birth weight. A new Maternal and Infant Health Branch has been created to provide support and focus for this effort. Eight professionals have been assigned to this Branch. One of the branch's major responsibilities will be provision of consultation and technical assistance with perinatal and infant health issues.

Question. If so, how many visits have been made now and what kind of resources in terms of staff are available?

Answer. In addition to the Branch other PHS staff, including individuals in Regional Offices, with clinical expertise will participate in visits as appropriate. Individuals from the academic and the private sector are also involved in the effort. PHS is currently working with the American College of Obstetricians and Gynecologists to facilitate this component.

The most recent consultation visits were made to the States of Arkansas and Nevada. A visit is scheduled for the State of New Jersey in April. We are planning visits with the State of Missouri and Wayne County, Michigan. A number of additional requests have been received, including Ohio, Wyoming, Arizona, Tennessee and San Juan, Puerto Rico.

Smaller teams or individual visits have been made to Massachusetts, the District of Columbia, and the cities of Boston and Philadelphia.

As part of a related activity to assist the States with the development of appropriate data systems and analytic capability, the Division of Maternal and Child Health, in collaboration with the Center for Disease Control, has assigned an MCH epidemiologist to the State of South Carolina. Assignments will be made to three additional States this year.

Teens/Low Birthweight

Question. We know that unmarried teens are at highest risk for having low birthweight babies that fail to survive the first year of life. We learned from a study by the Center for Population Options that teen pregnancy costs this nation

$16.6 billion per year. That does not even count the cost of remedial education, educating the low birthweight children of teen mothers that have multiple handicaps, housing, and social services. And yet teen pregnancy is on the rise at an alarming rate.

I understand you are going to be consulting communities and states on this issue and pursuing research on the subject. What are the research initiatives you have in mind?

Answer. Teen pregnancy is indeed a costly problem, and the cost is most heartbreaking in terms of low weight births, fetal and infant deaths and lost opportunities for education and economic self sufficiency for many teen parents. Teen pregnancy is a very complex problem, and simple solutions are not going to solve it.

We have to know a lot more about the factors which influence teens to become sexually active, and about why these factors affect one teen one way, and another, another. For teens who are already sexually active, we have to know better how to enable them to protect themselves from pregnancy. We have to learn more about how to mitigate the effects on pregnant teens and their infants. This involves better understanding of ways to ensure early enrollment in prenatal care, to facilitate adoption, and to enable the teen mother to continue her education and preparation for a responsible life as an adult.

The Department has a number of research programs and efforts that are already looking at various facets of this problem. Departmental agencies that give a significant amount of attention to the problem of adolescent pregnancy include: the National Institute of Child Health and Human Development which supports valuable biomedical and behavioral research; the Alcohol, Drug Abuse, and Mental Health Administration which conducts relevant studies on teen risk-taking and self-destructive behavior. The Department also supports demonstration efforts focusing on identifying effective models of primary prevention and care through the Adolescent Family Life program.

Questions Submitted by Senator Quentin N. Burdick

CHILDHOOD VACCINES

Question. I am happy to see that your emphasis at HHS is going to be on helping families. I share your belief that the family unit is our society's strongest building block, and believe we must provide funding for programs that benefit the family.

One issue that is proving very troublesome is childhood vaccines. The cost of essential vaccines such as DPT and MMR (measles/mumps/rubella) has risen in the past six years by as much as 3000 percent. What steps will your Department take to ease the current crisis in the availability, the cost, and the reserve supply of childhood vaccines?

Answer. The greatest threat to the supply and the ability to contain costs of vaccines remains the liability issue. To address

this, the Administration transmitted legislation to the Congress last year to ban punitive and limit non-economic awards against vaccine manufacturers. These limitations would enable insurers to better predict likely losses, thus allowing the manufacturers to continue to obtain liability insurance. We believe that this legislation would greatly reduce the threat of vaccine manufacturers leaving the market, and could encourage other manufacturers to enter the market. This could not only increase the availability of vaccine, but also help contain the increasing cost.

We are also expecting a second manufacturer of oral polio vaccine to enter the market this summer, and it is possible that a second manufacturer of measles-mumps-rubella vaccine will also enter the market. If liability insurance is obtainable, one of the diptheria-tetanus-pertussis vaccine manufacturers may decide to re-establish marketing. We expect that such increases in suppliers will reduce the possibility of vaccine shortages and foster competition in prices.

In addition, to ease cost pressures on public immunization programs, Federal contracting officials are continuing to negotiate lower prices for vaccines bought with public sector funds through consolidated contracts. For example, while the contract prices of vaccines have increased overall approximately 94% from the previous contract, this negotiated price still reflects a decrease of approximately 74% from the contractor's standard price list.

When projected 1986 acquisitions are delivered, the CDC vaccine stockpile will contain an average 17-weeks supply of the major childhood vaccines. This stockpile will provide an emergency supply of vaccine in the event of short term interruptions in vaccine supply. However, this stockpile is not designed to be an answer to the greater threat of manufacturers withdrawing completely from the market due to liability concerns.

VACCINE LIABILITY ISSUE

Question. Manufacturers' liability for vaccines is one cause of the tremendous cost increases. Do you have any plans to deal with the liability issue, so that the American public will be assured a safe and effective supply of these essential vaccines?

Answer. The Administration already transmitted legislation to the Congress last year proposing to ban punitive and limit non-economic awards against vaccine manufacturers. These limitations would enable insurers to better predict likely losses, thus allowing the manufacturers to continue to obtain liability insurance. If enacted, this legislation would greatly reduce the threat of vaccine manufacturers leaving the market, and could encourage other manufacturers to enter the market. This could not only increase the availability of vaccine, but also help contain increasing costs.

NURSING

Question. How can federal support for nursing research be eliminated when it has been shown to save taxpayers' dollars in the

long run? For example, nursing research on the care of premature infants resulted in treatment that reduced their length of hospital stay by an average of four days. The average cost of neonatal intensive care is estimated to exceed $13,000 and almost seven percent of newborns in the U.S. are at risk because of low birthweight.

Answer. Elimination of a line item for support of nursing research should not be viewed as an assessment by the Department that studies supported previously were ineffective. Well done studies like the one you described should continue to compete successfully for research support from NIH, ADAMHA, or NCHSR with the elimination of the Nursing Center.

Question. Congress authorized and appropriated monies for new nursing demonstration projects to address concerns about access to nursing services. Has this program been implemented yet?

Answer. The program has not been implemented, pending the outcome of the proposed rescission.

Question. A 1983 Institute of Medicine (IOM) report concluded that nurses with high quality graduate education are a scarce resource. The report recommended an increase in the number of nurses with skills commensurate with "the growing complexity of care in many health settings." The Administration's contention that there is an adequate supply of registered nurses does not acknowledge the fact that these monies are targetted at preparing nurses at the masters and doctoral levels -- not at the general level of practice. There are not sufficient numbers, for example, of nurse midwives, nurse practitioners, nurse anesthetists, nurse researchers, clinical nurse specialists in geriatric practice. The distinction must be made that federal funds for these nursing education programs are still needed. How can the Administration ignore the IOM recommendations and recommend eliminating funding for nursing education programs?

Answer. Individuals undertaking advanced nurse education have an earning capacity and can be expected to finance their further education as do other graduate students from more general sources of Federal and non-Federal student assistance.

Questions Submitted by Senator Daniel K. Inouye

NATIVE HAWAIIAN AND PACIFIC BASIN HEALTH CARE NEEDS

Question. We would appreciate learning the status of two reports which are being developed by your Department in response to the Committee's earlier expression of interest. The first highlights the unique health care needs of Native Hawaiians and, the second addresses the Federal responsiblity for providing quality health care to the residents of the Pacific Basin region.

Answer. The two reports requested by the Senate Appropriations Committee are nearing completion. The first, a report titled "Health Care Needs of Native Hawaiians", is based upon a study which began late in calendar year 1984. This report

includes data privided by the University of Hawaii and an analysis of health care issues prepared by the Native Hawaiian Health Research Consortium. The analysis was sent to PHS in late 1985 and a draft report was prepared and is presently under review by the operating agencies of the PHS. The final report is expected to be sent to Congress by May 1, 1986. The second, a report by the Pacific Basin Health Services, was sent from the PHS to the Secretary. This report includes consideration of the Compacts of Free Association with the Federated States of Micronesia, the Republic of the Marshall Islands and the Republic of Palau. This has necessitated additional time and review. The report is expected to be transmitted to Congress by April 15, 1986.

NURSING EDUCATION AND RESEARCH

Question. According to recent data collected by the American Association of Colleges of Nursing, enrollments in generic baccalaureate nursing programs have declined 7.6 percent between Fall, 1984 and Fall, 1985. Nursing shortages are once again being felt and are predicted to become more problematic due to decreasing enrollments. Federal support is critical to the survival of many nursing programs, and the President's budget proposes rescission of most of the Division of Nursing 1986 funds and total elimination of these funds in 1987. Oversupply statistics pertinent to physicians do not apply to nursing. Therefore, what rationale does the Administration have for rescission and then elimination of funds for nursing education and research?

Answer. The most reliable information regarding trends in admissions and enrollments in schools of nursing is provided by the Annual Survey of the National League for Nursing covering all schools of nursing. The latest information is for the academic year 1983-84 in which admissions of generic students to baccalaureate programs increased by 5.7% over the previous year. Total enrollments are a less reliable indicator of trends because they are affected by numerous factors such as changes in length of program and attrition rates.

Evidence presented in the Fifth Report to the Congress on the Status of Health Professions in the U.S. found no aggregate imbalance between supply and requirements in the foreseeable future. Profound changes in the health care delivery system could alter the supply-demand equation, but there is no quantifiable evidence to date to document the impact of such changes.

Question. What evidence does the Administration have indicating that other funding sources are available to replace Federal funding for nursing education and research?

Answer. The past twenty years of federal support has substantially increased the capability of schools of nursing to add to the nurse supply. Baccalaureate programs are now firmly established in academic settings and have available to them the same resources as are used for other health disciplines.

NATIONAL CENTER FOR NURSING RESEARCH

Question. NIH staff are moving ahead to develop a Legislative Implementation Plan for the new National Center for Nursing Research. If 1986 funding for the Center is to be rescinded and elimination of funding is to be effected in 1987, what are the Administration's plans, including timetables, to establish the new Center?

Answer. The timetable for establishing the new Center is dependent upon the resolution of the President's rescission package pending before Congress. The NIH would expect to initiate a Search and Screen Committee to identify an NCNR Director as soon as the request to establish the position is approved.

Questions Submitted by Senator Tom Harkin

IMPACT OF THE PROSPECTIVE PAYMENT SYSTEM ON MEDICARE BENEFICIARIES

Question. Could you tell me what has been the impact of the Medicare prospective payment system on the quality of health care for recipients?

Answer. The prospective payment system has built-in safeguards to assure that the quality of care for Medicare beneficiaries meets professional standards. Utilization and Quality Control Peer Review Organizations (PROs) are responsible for monitoring the quality of care given to Medicare patients in the hospital setting. PROs are required to identify quality of care issues and to investigate and correct any improprieties they find. Under the new Scope of Work, to be signed in 1986, we have substantially intensified the quality of care aspects of PRO review. Under the Scope of Work, PROs will:

- o subject every case they review to generic quality screens,
- o review services at certain hospitals identified as having unexplained or unexpected utilization and mortality rates, or other problems,
- o identify and focus their review on practitioners who practice poor quality care,
- o review readmissions within 15 days of discharge to determine whether patients are released too early, and
- o determine the appropriateness of the discharge in every case they review.

In addition, HHS is conducting studies of a broad range of issues related to quality and access to care under PPS. Some of these include: possible changes in patient care outcomes associated with PPS, appropriateness of lengths of hospital stays and treatment patterns, and access to post-discharge sub-acute services. While hospital length of stay dropped significantly in FY 1984, the year in which the Medicare Prospective Payment System (PPS) began to be phased-in, there

is no evidence available, to date, indicating a systematic change in the quality of care associated with PPS implementation.

Question. The Director of Acute Care Regulation with the Iowa Foundation for Medical Care, the Iowa Peer Review Organization, said that premature discharges are the biggest problem they are currently seeing in Iowa. Are Medicare patients being discharged too soon and too sick as a result of the prospective payment system? Have you done any studies on this?

Answer. The Iowa PRO has no systematic evidence that patients are being discharged too soon and too sick as a result of the prospective payment system. However, the Iowa PRO's posture is aggressive in identifying premature discharges and their physicians are committed to this.

The Health Care Financing Administration, in conjunction with the Assistant Secretary for Planning and Evaluation, is initiating a major study which focuses on developing a reliable method for assessing whether Medicare patients are being appropriately discharged from the hospital. Specifically, this study will assess patients' health status and dependency at discharge and evaluate the adequacy, accessibility and use of post-discharge services.

Currently, other than ancedotal evidence, there are not conclusive data available concerning the issue of whether PPS is inducing hospitals to discharge Medicare patients too soon and too sick, on a system-wide basis.

PROSPECTIVE PAYMENT SYSTEM (PPS) WAGE INDEX

Question. Rural and urban hospital administrators have pointed out the faults in using Bureau of Labor Statistics (BLS) data to develop the urban and rural diagnosis related group rates. For example, Bureau data does not include part-time employees, on whom rural hospitals rely heavily.

It is my understanding that a new "gross wage index" --one which better accounts for part-time employees -- is to be implemented after March 14 of this year. Is this correct? If not, when will it be implemented?

Answer. The Department of Health and Human Services has long been aware of the problems with BLS wage data. Our concerns were pointed out in our March 29, 1985 report to Congress. Our changes in 1986 PPS rates (FR 35646, September 3, 1985) included a revised wage index that responded to many of these concerns. However, implementation of the new rates has been postponed by the Emergency Extension Act. The Emergency Extension Act expires March 14, and as of this time, the Department is awaiting congressional action.

Catastrophic Illness

Question: You have stated that you favor Medicare coverage for elderly patients with catastrophic illnesses. What do you consider a catastrophic illness?

Would you consider similar coverage for younger patients with catastrophic illnesses?

Answer: In our opinion, catastrophic illness is best thought of as illness requiring out-of-pocket expenditures that would lead to financial ruin for the beneficiary or the beneficiary's family.

There are many conflicting definitions of catastrophic illness. For example, various observers have described catastrophic illness as:

- o One of a number of specific diseases or conditions (such as renal disease or cancer), sometimes limited to those treated by certain types of medical services.
- o An illness requiring insured medical expenses, or out-of-pocket medical expenses, above a specific dollar figure.
- o An illness requiring levels of expenditure that represent a certain percent of income. This percentage may reflect different degrees of financial consequences, ranging up to total bankruptcy.

It is for precisely this reason — the lack of concensus on the vary nature of the problem -- that the President has set asisde this year to make a detailed analysis of the issue.

Nursing Education

Question. In the 1984 Fourth Report to the Congress on the Status of Health Personnel, the Department of Health and Human Services recommended continued Federal support for nursing education programs, in the words of the report, -- to assist in filling the unmet needs for nurses prepared as teachers, administrators, or clinical specialists. How can the Department reverse its position on this issue by allowing the Administration 1987 budget to eliminate Federal funding for nursing education programs?

Answer. The Administration must always reevaluate competing priorities for Federal support. In view of the past Federal investment in advanced nurse education training, we believe that these programs have been institutionalized into the nursing educational system and will be available for those individuals desiring to become teachers, administrators or clinical experts.

SUBCOMMITTEE RECESS

Senator WEICKER. The subcommittee will now stand in recess until tomorrow morning, March 5, at 10:30. That is a change from the originally announced time. It will convene at 10:30 and we will meet again in this room and at that time we will begin our hearings on the budget request for the National Institutes of Health, and we will hear the Director's overview and we will hear from the National Cancer Institute, the National Institute of Allergy and Infectious Diseases, and the National Institute on Aging, and Division of Research Sources.

Now, I would like to request both of the Secretary and also give advance warning to those who are going to testify before the committee, that the committee will expect from the various components of the agency those budgets that were submitted to OMB, prior to OMB action, prior to final action. We want to know exactly what the submission consisted of prior to further administration action. And I alert everybody to the fact that the information will be requested.

I thank you all very much and we will see you in the morning.

[Whereupon, at 12 noon, Tuesday, March 4, the subcommittee was recessed, to reconvene at 10:30 a.m., Wednesday, March 5.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1987

WEDNESDAY, MARCH 5, 1986

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:30 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker, Andrews, Specter, and Proxmire.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF DR. JAMES WYNGAARDEN, DIRECTOR

ACCOMPANIED BY:

DR. WILLIAM F. RAUB, DEPUTY DIRECTOR FOR EXTRAMURAL RESEARCH AND TRAINING

NORMAN D. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT

DENNIS P. WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

OPENING STATEMENT OF SENATOR WEICKER

Senator WEICKER. The subcommittee will come to order.

We begin today 3 days of hearings that will focus on the President's proposed budget for the National Institutes of Health. This budget cuts funding for NIH by $400 million.

When the estimated cost of disease to this Nation is $400 billion, I don't see how we can afford to reduce the funding for biomedical research by one penny.

The NIH is the world's premier biomedical research institution. It has been and continues to be responsible for the unique quality of healthy life enjoyed by the citizens of this Nation and by the citizens of the Western World. We continue to hear of scientific opportunity and advances made at NIH such as cell transplantation in diabetes, a vaccine

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for malaria, and a recent identification of a chemical trigger in the virus that causes AIDS. In fact, a few short months ago a new and promising cancer therapy was announced by the National Cancer Institute.

But, despite NIH's unprecedented biomedical accomplishments, there is still a lot of work to be done. New cases of AIDS continue to be reported; cancer still claims the lives of more than 450,000 people each year, and almost twice that number die of heart disease. The question is not whether we will discover cures for these diseases but when. The knowledge exists; the breakthroughs are occurring—what is needed are the dollars to fund our research efforts.

I welcome Jim Wyngaarden, who does an outstanding job at NIH as its Director. I am looking forward to your opening statement.

At this point I would like to say that all the statements of the directors of the separate institutes will be included in the record in their entirety.

Please proceed.

PRESENTATION OF NIH REQUEST

Dr. WYNGAARDEN. Thank you, Senator Weicker.

Mr. Chairman, it is my privilege to present the President's budget proposal for NIH for fiscal year 1987. Before doing so, I want to add a personal observation that, during the time I have been Director of NIH, I have been impressed with the level of interest and understanding with which you, your colleagues, and the staff of the subcommittee deal with matters affecting NIH. We just want you to know that we appreciate that.

NIH CENTENNIAL

Fiscal year 1987 will be observed as NIH's centennial year. In August 1887, the one-room National Laboratory of Hygiene was opened at the Marine Hospital on Staten Island to study cholera and other infectious diseases. Thus began what is described in our centennial slogan as "A Century of Science for Health." After several changes in name and location, the National Laboratory of Hygiene became the National Institutes of Health.

We see the centennial year as much more than an institutional birthday, but rather as an occasion for creating a better understanding among the American people of the importance of biomedical research—an opportunity to convey a sense of its accomplishments and promise.

RESEARCH ADVANCES

Among those accomplishments are tremendous advances against acquired immunodeficiency syndrome. Special attention is being given to involving additional scientific groups and additional AIDS patients in these efforts. The NCI and the NIAID are planning to fund national cooperative drug discovery groups, aimed at discovery of effective agents to interfere with replication of the AIDS virus and at restoration or maintenance of the immune response.

The NIAID also plans to establish AIDS treatment evaluation units in various locations for the testing of antivirals, immune modulators, and antibiotics in AIDS patients. At the same time, NIH intramural and grant-supported scientists are actively pursuing a variety of scientific approaches to the development of vaccines.

Simultaneously, we are learning a great deal more about the basic structure of the virus itself, how it controls its replication, how it destroys certain target cells. These new insights may prove crucial to development of effective agents for prevention and treatment.

An NIH research team, led by Dr. Steven Rosenberg, has developed a new approach to cancer treatment using interleukin–2 to activate the immune system to destroy cancer cells. The original study in 25 patients has been expanded through funding at six medical centers where about 300 additional patients will be treated.

We are also making gains against genetic diseases. Recently, NIH scientists, working with investigators elsewhere, found a genetic marker for cystic fibrosis, the most common fatal inherited disease of caucasians.

Another major advance has been made in understanding of the genetic neuromuscular disease Duchenne muscular dystrophy [DMD]. Scientists have recently cloned a DNA fragment that detects a defect in or near the DMD gene. This work forms the basis for much more accurate detection of female carriers of the gene and for prenatal diagnosis.

Great strides have also been made against the complications of diabetes, understanding the role of enzyme aldose reductase in the development of the cataracts common in diabetes. Another approach, transplantation of donor pancreas islet cells to replace those lost in diabetes, is progressing with exciting rapidity.

SAVINGS IN HEALTH CARE COSTS

As you know, there is growing concern about the rising costs of health care and the impact of biomedical research on these costs. Undeniably, certain fruits of research—especially technological advances—initially may appear to increase health care costs. You perhaps would be interested in an informal survey we conducted recently at NIH, looking for examples of advances in biomedical sciences that have reduced health care costs. A selection of just 12 recent advances were estimated to save about $2.5 billion annually in health care costs.

Among these examples were drug treatment rather than surgery for patent ductus arteriosus, a serious heart defect of infants; drug treatment of coronary artery disease instead of coronary bypass surgery in certain patients; and newly developed laser treatment for serious eye diseases.

ADJUSTMENTS IN FISCAL YEAR 1986 BUDGET

Mr. Chairman, we understand the need for strong measures to reduce the Federal deficit. The budget we present is an example of the kind of restraint the times require. At the same time, we are well aware of the potential impact of the fiscal year 1987 request and will do our best to

maintain the stability of the Nation's biomedical research enterprise and the momentum of its recent progress. To do so will require maximum flexibility so that we can make maximum use of our resources to take advantage of scientific opportunities.

Before proceeding to a discussion of the fiscal year 1987 proposal, however, it is necessary to take into account certain adjustments in the fiscal year 1986 budget. The first such modification is a reduction of $236.2 million, as required by the Balanced Budget and Emergency Deficit Control Act.

This 4.3-percent decrease has been applied uniformly against the appropriation of each NIH Institute, as well as against each research mechanism at the NIH aggregate level, and each identified program, project, or activity.

In addition, three rescissions are proposed totaling $76.8 million in fiscal year 1986 budget authority. These rescissions call for a decrease of $53.7 million from research project grants as part of a new stabilization policy, a decrease of $13.9 million appropriated to the Office of the Director for AIDS research, and a decrease of $9.1 million from the small and minority universities and colleges program. The small and minority schools programs will be continued at the fiscal year 1985 level.

FISCAL YEAR 1987 BUDGET REQUEST

The fiscal year 1987 budget request for NIH is $4,936,157,000, a decrease of $131,206,000 or 2.6 percent from $5,067,363,000, which is the comparable fiscal year 1986 total after deducting for the Balanced Budget Act and the fiscal year 1986 proposed rescissions.

With this presentation of the fiscal year 1987 budget, the administration proposes a new research grant stabilization policy. Under this new policy, the total number of NIH research project grants would be stabilized at 18,000 grants. This is a departure from the previous stabilization policy where the goal was to stabilize the number of competing awards.

The fiscal year 1987 request would include support for 18,000 grants of which 5,140 would be competing awards. This compares with 18,357 total grants awarded in fiscal year 1985 and 18,195 such awards projected for fiscal year 1986.

A new method of reimbursing grantees for the indirect cost portion of NIH grant awards is assumed with the fiscal year 1987 budget. The new fair share allocated overhead policy would set a national maximum limit for academic grantees on the reimbursement rate for the administrative overhead costs that constitute approximately one-half of all indirect cost reimbursements to these institutions.

Beginning in fiscal year 1987, the new policy would cap reimbursement for such administration at 20 percent of the grant's direct costs, as compared with the current average of 26 percent for this element.

The request for $198.2 million for research training will support about 9,250 predoctoral and postdoctoral trainees, a reduction of 700 trainees from the proposed fiscal year 1986 level of 9,950. The total number of research centers in fiscal year 1987 would be decreased by 11 to a total of 523.

Other extramural NIH research mechanisms will be maintained at approximately their fiscal year 1986 funding levels. Two exceptions are the Biomedical Research Support Grant Program and the extramural facilities construction programs, both of which will be eliminated in fiscal year 1987.

Intramural research at NIH in 1987 will be funded at $548.4 million, an increase of $11.5 million, or 2 percent above the comparable 1986 level.

The 1987 budget request for NIH excludes all funding related to acquired immunodeficiency syndrome. All fiscal year 1987 resources for AIDS are being requested for appropriation to a single account in the Office of the Assistant Secretary for Health.

In closing, permit me to call attention to the fiscal year 1987 budget proposal for the National Institute for Arthritis, Musculoskeletal and Skin Diseases. Details regarding the planned activities of the new Institute will be presented later in the hearings. I believe the committee will also be interested in knowing that the Public Health Service is developing an implementation plan for the establishment of the National Center for Nursing Research at NIH.

Mr. Chairman, I will be pleased to answer any questions you may have.

PREPARED STATEMENT

Senator WEICKER. Thank you very much, Dr. Wyngaarden. Before we proceed with some questions we will insert your prepared statement in the record in its entirety.

[The statement follows:]

STATEMENT OF DR. JAMES WYNGAARDEN

Mr. Chairman, it is my privilege to present the President's budget proposal for the National Institutes of Health (NIH) for Fiscal Year 1987, and to outline briefly our activities and plans. In doing so, I wish to add a personal observation that during the time I have been Director of the National Institutes of Health, I have been impressed by the level of interest and understanding with which you, your colleagues, and the staff of the Subcommittee deal with matters affecting the National Institutes of Health.

Fiscal 1987 will be observed as NIH's centennial year. In August of 1887, the one-room National Laboratory of Hygiene was opened at the Marine Hospital on Staten Island to study cholera and other infectious diseases, hoping that from the research could be found the means for fighting such devastating diseases. Thus began what is described in our centennial slogan as "A Century of Science for Health." For after several changes in name as well as location, the National Laboratory of Hygiene became the National Institutes of Health.

American science in the 1880s was rooted in the work and inspiration of the European giants Robert Koch and Louis Pasteur. It is fortuitous that the centennial of the Pasteur Institute coincides with that of the NIH. In May of the next year, Pasteur and the NIH will hold a symposium on molecular biology in Bethesda as a joint celebration of this important anniversary. Other centennial events are scheduled at various times during the year, including regional salutes to the federal/academic partnership in biomedical research so successfully nurtured by the NIH. These locally sponsored celebrations will be held in such centers of research as Boston, St. Louis, Atlanta, and San Francisco. We see the NIH centennial as much more than an institutional birthday, but rather as an occasion for creating a better understanding among the American people of the importance of biomedical research--an opportunity to convey a sense of its accomplishments and promise.

Among those accomplishments are tremendous advances against acquired immune deficiency syndrome (AIDS). Special attention is being given to involving additional scientific groups and additional AIDS patients in these efforts. The National Cancer Institute and the National Institute of Allergy and Infectious Diseases (NIAID) are planning to fund National Cooperative Drug Discovery Groups, aimed at discovery of effective agents to interfere with replication of the AIDS virus and at restoration or maintenance of the immune response. The NIAID also plans to establish AIDS Treatment Evaluation Units in various locations for the testing of antivirals, immune modulators, and antibiotics in AIDS patients. At the same time, NIH intramural and grant-supported scientists are actively pursuing a variety of scientific approaches to the development of vaccines.

Simultaneously, we are learning a great deal more about the basic structure of the virus itself, how it controls its replication, how it destroys certain target cells. These new insights may prove crucial to the eventual discovery of effective agents for prevention and treatment of AIDS.

The AIDS screening test for donated blood, based on the work of Dr. Robert Gallo of the National Cancer Institute, has provided a means for safegarding hemophiliacs from AIDS. This test and development of a method for pre-treating Factor VIII against HTLV-III has resulted in a remarkable reduction in risk for hemophiliacs. Studies have shown that in some hemophilia populations over 90 percent of hemophiliacs had developed antibodies to HTLV-III. Several recent studies show that of hemophiliacs who had received only treated Factor VIII, none has developed antibodies to the AIDS-causing virus.

An NCI research team, led by Dr. Steven Rosenberg, has developed a new approach to cancer treatment using interleukin-2 to activate the immune system to destroy cancer cells. The original study in 25 patients has been expanded through funding at 6 medical centers where about 300 additional patients will be treated.

Researchers are making gains against genetic diseases. Recently, NIH scientists, working with investigators elsewhere, found a genetic marker for cystic fibrosis, the most common fatal inherited disease of Caucasians. This discovery permits the identification of most carriers of the disease within families having a history of the disease, and brings scientists closer to finding the gene itself and to discovering the basic defect causing cystic fibrosis. Another major advance has been made in understanding of the genetic neuromuscular disease Duchenne muscular dystrophy (DMD). Scientists have recently cloned a DNA fragment that detects a defect in or near the DMD gene. This work forms the basis for much more accurate detection of female carriers of the gene and for prenatal diagnosis.

Great strides are also being made against the complications of diabetes. Scientists are beginning to understand the role of the enzyme aldose reductase in the development of the cataracts common in diabetes. This research has led to the evaluation of aldose reductase inhibitors--drugs now being tested in clinical trials for the prevention of diabetic eye disease and other complications as well. Research has provided other new treatment options and new hope for the individual at risk for the most serious complications of diabetes. Examples include laser treatment for diabetic retinopathy and improvements in kidney dialysis. Another treatment approach, transplantation of donor pancreas islet cells to replace those lost in diabetes, is progressing with exciting rapidity. Such transplantation of pancreas tissue offers great hope for providing recipients with a close facsimile of the normal function of the pancreas.

As you know, there is growing concern about the rising costs of health care and the impact of biomedical research on these costs. Undeniably, certain fruits of research--especially technological advances--initially may appear to increase health care costs. You will perhaps be interested in an informal survey we recently conducted at the NIH looking for examples of advances in biomedical research that have reduced health care costs. A selection of just 12 recent advances were estimated to save about $2.5 billion annually in health care costs. Among these examples were drug treatment rather than surgery for patent ductus arteriosus, a serious heart defect of infants; drug treatment of coronary artery

disease instead of coronary bypass surgery in certain patients; and newly developed laser treatment for serious eye diseases.

Mr. Chairman, we understand the need for strong measures to reduce the federal deficit. The budget we present is an example of the kind of restraint the times require of the non-exempt components of the Government. At the same time, we are well aware of the potential impact of the FY 1987 request and will do our best to maintain the stability of the Nation's biomedical research enterprise and the momentum of its recent progress. To do so will require maximum flexibility so that we can make maximum use of our resources to take advantage of scientific opportunities.

Before proceeding to a discussion of the FY 1987 proposal, however, it is necessary to take into account certain adjustments in the FY 1986 budget. The first such modification is a reduction of $236.2 million, as required by the Balanced Budget and Emergency Deficit Control Act. This 4.3 percent decrease has been applied uniformly against the appropriation of each NIH institute, as well as against each research mechanism at the NIH aggregate level, and each identified program, project or activity. In addition, three rescissions are proposed totaling $76.8 million in FY 1986 budget authority. These rescissions call for a decrease of $53.7 million from research project grants as part of a new stabilization policy, a decrease of $13.9 million appropriated to the Office of the Director for AIDS research, and a decrease of $9.1 million from the small and minority universities and colleges programs. The reduction in project grants is a necessary transition to the spending levels in the 1987 President's budget. The small and minority schools programs will be continued at the FY 1985 level.

The FY 1987 budget request for NIH is $4,936,157,000, a decrease of $131,206,000 or 2.6 percent from $5,067,363,000 which is the comparable FY 1986 total after deducting for the Balanced Budget Act and the FY 1986 proposed rescissions.

With this presentation of the FY 1987 budget the Administration proposes a new research grant stabilization policy. Under this new policy the <u>total</u> number of NIH research project grants would be stabilized at a total of 18,000 grants. Almost 57 percent of the total proposed NIH budget is allocated for such grants. This is a departure from the previous stabilization policy where the goal was to stabilize the number of competing grants. Thus the FY 1987 request would include support for 18,000 grants of which 5,140 would be competing awards. This compares with 18,357 total grants awarded in FY 1985 and 18,195 such awards projected for FY 1986.

A new method of reimbursing grantees for the indirect cost portion of NIH grant awards is assumed with the FY 1987 budget. This proposal reflects the commonly expressed concerns of both the Congress and the Administration over the escalating costs of research. The new "Fair Share Allocated Overhead Policy" would set a national maximum limit for academic grantees on the reimbursement rate for the administrative overhead costs that constitute approximately one-half of all indirect cost reimbursements to these institutions. Beginning in FY 1987, the new policy would cap reimbursement for such administration at 20 percent of the grant's direct costs, as compared with the current average of 26 percent

for this cost element. Implementation of the new policy is expected to reduce indirect costs by an estimated $85 million.

The request for $198.2 million for research training will support about 9,250 predoctoral and postdoctoral trainees--a reduction of 700 trainees from the proposed FY 1986 level of 9,950. The number of research centers in FY 1987 would be decreased by 11 to a total of 523 and the funding for the centers would be reduced by an aggregate of 4 percent from the 1986 funding level.

Other extramural NIH research mechanisms will be maintained at approximately their FY 1986 funding levels. Two exceptions are the Biomedical Research Support Grant (BRSG) Program and the Extramural Facilities Construction Programs, both of which will be eliminated in FY 1987. Because of the continued emphasis on investigator-initiated project grants as the most appropriate form of support, and in the face of growing concern over budget restraints, the BRSG must rank as a lower priority when compared with other NIH programs. The Extramural Facilities Construction Program is also proposed for elimination due to budgetary constraints and the relatively lower priority of this program. Intramural research at the NIH in 1987 would be funded at $548.4 million, an increase of $11.5 million or 2 percent above the comparable FY 1986 level.

The FY 1987 budget request for NIH excludes all funding related to acquired immune deficiency syndrome (AIDS). All FY 1987 resources for AIDS are being requested for appropriation to a single account in the Office of the Assistant Secretary for Health (OASH), who will have the responsibility to allocate these funds to the several PHS agencies participating in AIDS research, prevention, and treatment. Estimates of the number of NIH research project grants on AIDS, to be supported from the OASH fund, are included in the numbers of grants counted against the stabilization objective.

In closing, permit me to call attention to the FY 1987 budget proposal for the National Institute for Arthritis, Musculoskeletal and Skin Diseases. Details regarding the planned activities of the new institute will be presented later in the hearings. I believe the committee will also be interested in knowing that the Public Health Service is developing an implementation plan for the establishment of the National Center for Nursing Research at the NIH.

I will be pleased to answer any questions you may have.

CHRONOLOGY OF THE BUDGET REQUEST

Senator WEICKER. First of all, do you have the budget which you requested, your original budget request before it was given back to you by OMB?

Dr. WYNGAARDEN. Are you requesting the NIH request to the PHS, and from the PHS to the Department?

Senator WEICKER. In other words, when you make your budget presentation, you devise these figures within your own body first, don't you?

Dr. WYNGAARDEN. Yes; we do.

Senator WEICKER. What is the first stop along the line, as far as the administration is concerned, does it go directly to OMB?

Dr. WYNGAARDEN. No; we first present our budget to the Public Health Service, which integrates it with other agency budgets, and presents that to the Department, which integrates the PHS request with other departmental budgets, and then presents the entire package to OMB. Three separate figures are involved.

Senator WEICKER. I don't want to waste any more time than is necessary. Was there much of a change from your presentation to PHS and when it left the Department, or did the change take place from the Department to OMB?

Dr. WYNGAARDEN. There was some change at each level.

Senator WEICKER. Maybe we ought to have that for the record.

Dr. WYNGAARDEN. The NIH estimate to PHS was $6,415,088,000; the PHS estimate to the Department was $6,093,456,000; and the Department estimate to OMB was $5,907,355,000.

Senator WEICKER. Then what came back?

Dr. WYNGAARDEN. The President's budget came to us as $4,936,157,000, but that excludes the AIDS transfer of $143 million to the OASH budget.

Senator WEICKER. You say that $143 million went to the OASH?

Dr. WYNGAARDEN. Yes.

Senator WEICKER. So that would roughly put you at $5.079 billion.

Dr. WYNGAARDEN. Yes.

Senator WEICKER. Your original request was a $6.4 billion figure.

Dr. WYNGAARDEN. Yes.

Senator WEICKER. And we are ending up with $5.1 billion.

Let me continue along that line. For example, hitting some of the highlights here, your initial request what did it call for in the way of grants?

Dr. WYNGAARDEN. That was about 8,500 competing grants.

Senator WEICKER. Let me tell you what we had better have, each of the institutes can speak for themselves, but I would like to see a breakdown between the—I am just trying to think. I don't want to impose on you more than is necessary, but I would certainly like to see the initial request made of PHS.

The departmental budget at $5.9 billion, that figure, that was out of the Secretary's office?

Dr. WYNGAARDEN. Yes; to OMB.

Senator WEICKER. I would like to see the three stages, the $6.4 billion, the $5.9 billion, and the $5.1 billion, and the breakdowns that occurred during that process.

Dr. WYNGAARDEN. What do you mean by breakdowns?

Senator WEICKER. In other words, by function. I would like to see the three stages.

[The information follows:]

CHRONOLOGY OF THE 1987 BUDGET

[In thousands of dollars]

	NIH estimate to PHS		PHS estimate to Department[1]		DHHS estimate to OMB		President's budget[2]	
	Number	Amount	Number	Amount	Number	Amount	Number	Amount
Research grants:								
Research projects:								
Noncompeting	10,745	$1,930,169	12,994	$2,324,571	13,172	$2,344,571	12,785	$2,003,507
Admin. supp	(459)	13,719	(406)	12,532	(381)	12,532	(399)	15,200
Competing	8,500	1,392,310	6,500	1,101,226	6,000	1,020,713	5,104	784,541
Subtotal, competing	8,500	1,392,310	6,500	1,101,226	6,000	1,020,713	5,104	784,541
Subtotal, research project grants	19,245	3,336,198	19,494	3,438,329	19,172	3,377,816	17,889	2,803,248
Research centers:								
Spec/comp	422	437,363	343	343,439	349	350,164	340	295,403
GCRC	80	97,867	79	95,706	78	98,445	76	86,082
Biotech	58	37,550	54	33,365	61	37,770	60	33,898
LASPR	44	43,037	46	37,110	46	33,252	46	29,905
Gorgas	1	2,173	1	2,173	1	2,151	1	1,934
Subtotal, centers	605	617,990	522	511,793	535	521,782	523	447,222
Other research:								
Careers	1,618	100,952	1,384	83,562	1,334	81,861	1,270	76,249
Organ sys	1	1,042	1	1,042	3	2,770	1	800
Clin. ed	69	7,000	51	5,303	51	5,210	39	2,400
Coop. cl	358	75,265	298	63,300	303	54,039	256	51,876
BRS	741	114,697	701	104,697	727	100,381	154	32,883
MBRS	89	44,298	81	41,000	79	36,532	92	33,642
Other	795	78,792	590	57,888	547	43,474	489	39,684
Subtotal	3,671	422,046	3,106	356,792	3,044	324,267	2,301	237,534
Total, research grants	23,521	4,376,234	23,122	4,306,914	22,751	4,223,865	20,713	3,488,004

Training:								
Indiv	1,608	43,654	1,412	40,791	1,489	35,444	1,292	30,630
Instit	8,892	204,771	8,588	191,341	8,663	185,244	7,966	167,574
Total	10,500	248,425	10,000	232,132	10,152	220,688	9,258	198,204
Contracts	1,544	509,287	1,337	434,658	1,317	446,021	1,192	328,458
Intramural		681,082		658,994		612,565		548,357
RM&S		241,464		222,082		221,167		210,894
Control		102,939		70,244		64,575		61,131
Construction		84,349		40,349		3,125		
Total, IRD's		6,243,780		5,965,373		5,792,006		4,835,048
National Library of Medicine		76,675		71,131		59,115		56,408
Office of the Director		42,833		41,312		37,757		36,701
Buildings and facilities		51,800		15,640		18,477		8,000
Total, NIH		6,415,088		6,093,456		5,907,355		4,936,157

[1] The base used for the development of these submissions was the 1986 President's budget of $4,852,680.
[2] Excludes $143,868 in AIDS research funding proposed for transfer to OASH.

PUBLIC AWARENESS

Senator WEICKER. I think that it is very fortuitous, very frankly, that you are celebrating your centennial, and I want to get to that in just 1 minute, what it is that you intend to do to bring your work at NIH to the attention of the public. It is their dollars, and they ought to know what is going on.

I think because they don't know what is going on, that is the reason that they are not putting pressure on the administration to see that the Institutes' activities are conducted at the most optimum level.

BUDGET PRIORITIES

Certainly, it would seem inappropriate, during the centennial year, to take a step backward. I notice in your statement, you say that you understand the need for strong measures to reduce the Federal deficit, "The budget we present is an example of the kind of restraints the times require."

I don't understand the need to reduce your budget, and I don't see that these times require of you the extraordinary measures that are now required of others in the budget.

Again, I repeat the same comments that I made to the Secretary yesterday, which is that I, and I think many members of the subcommittee, come at this as a totally fresh picture, without any Gramm-Rudman mandatory cuts, and with us being able to go ahead and apply ourselves to the priorities in a way probably somewhat different than the administration.

That is what we are going to do during the course of these discussions over the next 3 days.

I think you are well aware, because of the fine work that you and your colleagues do, you enjoy an extraordinary support within the Congress of the United States. I, again, have to repeat, I think you are probably somewhat short insofar as enjoying the understanding of the people of this country.

NIH CENTENNIAL

What do you intend to do vis-a-vis this centennial of NIH? This is a departure for me, this is a great departure, because I will tell you, I am not much for public relations. I know no better example of that than myself. [General laughter.]

I think it is terribly necessary in the case of NIH to have the American people understand this great treasure that we have insofar as governmental activities are concerned. I think that it would make you far more immune to the cuts that are being proposed if they did know.

So I would like to know, what do you have planned vis-a-vis the education of the American public as to the activities of NIH?

Dr. WYNGAARDEN. We have a number of activities planned, Senator. The one that is directed most toward the American public is a series of 1-hour television specials. We plan to have these produced in several

scientific areas where there has been significant progress, such as cancer and heart disease. We haven't settled on all of them, but one might deal with virus production, and that kind of thing, which will highlight research both intramurally and extramurally. We want to have a theme that the American public will be interested in.

Television specials are expensive. We think we have the funding from non-Federal sources to produce them. We will know more about that in the next few weeks.

We plan also a series of centennial salutes in various parts of the country. These are primarily scientific presentations, but they will be at the level of the public, to some extent, and we will generate publicity in their holding. A number of these will be at the National Institutes of Health in the fall.

We will have one large reunion for former NIH scientists and public figures. We also plan a series of symposia with some professional societies. It turns out that this is an anniversary year for many other components. One example of that is the Pasteur Institute in Paris, and we plan a joint symposium with Pasteur scientists in Washington in the fall of 1987.

I think that those are the key points we have addressed to this point. We have an overall NIH committee, and we have also an extramural committee headed by Don Fredrickson who is the former NIH Director, together with a number of scientists, particularly those who have achieved positions of great prominence in industry, as part of this overall planning committee. We are well along with the plans.

PUBLIC RELATIONS

Senator WEICKER. Does NIH have its own press officer?

Dr. WYNGAARDEN. Yes.

Senator WEICKER. Is he or she here today?

Dr. WYNGAARDEN. No; he is not.

Senator WEICKER. I would appreciate it if, during the course of the next few days, that individual would appear before the committee so that we might have a discussion with them as to what is being done.

Dr. WYNGAARDEN. Fine. We will arrange for Mr. Whaley to be here.

Senator WEICKER. What is the situation vis-a-vis the public being able to see your facilities, and such work as might be appropriate?

Is there any provision made at all in that sense?

Dr. WYNGAARDEN. Yes; there is. We have groups that come from time to time. We also have a series of evening seminars on health issues for the public that are very well attended. We are happy to have any group that requests an opportunity to visit us. We have a visitor center and a small museum of largely obsolete instruments that are very interesting to discuss, leading them from the point of departure to the more complex instruments of today. We have people whose responsibility it is to deal with the public in this respect.

CELEBRATION OF THE CENTENNIAL

Senator WEICKER. I think that this is something that I want to pursue, Jim, with you, and also with your press people. I think that it is great that we are celebrating the Statue of Liberty. I think that it is very nice. I like it, and it is a great reminder of our past.

On the other hand, to me, the prospect of celebrating the future in terms of your centennial is even more exciting, to be quite candid. I see all the hoopla over the one, and I am chairman of the subcommittee, and I didn't know that it was your centennial until you mentioned it in your statement.

I really do want to do something about that, and having said that, I can assure the administration that this will not be the sum total of my celebration of your centennial. I intend to do that with significantly more money at the various institutes, and the ability to go ahead and move forward.

I do think that it is important and the moneys are not insubstantial. If the American public had a full appreciation of what is going on, and what can be accomplished, and where all of this activity should fit in the sense of our national priorities.

I have been a very privileged individual indeed to chair this committee. I dare say, were it not for the fact that NIH is under my aegis, I would probably have shifted to one of the other subcommittees a long time ago. But this is the work that the Government was meant to be about, and I think that it is entirely appropriate that the people know.

There is no mystery about our system of government. I know a lot of people criticize the people down in Washington, but the people in Washington are representative of what the American people want. I think that if the American people knew, believe me, they would want a lot more than what is being generated now, or what is in the administration's budget.

Dr. WYNGAARDEN. We are also trying, Senator, to have a commemorative stamp issued on the occasion of the centennial. That is in the request process.

RESEARCH PROJECT GRANTS

Senator WEICKER. At the postsequestered level of funding, NIH is now supporting 18,649 grants. This number includes both new and continuing grants; is that correct?

Dr. WYNGAARDEN. Yes.

Senator WEICKER. How many grants would NIH support if we maintained 6,100 new grants every year?

Dr. WYNGAARDEN. The average length of an award is now about 3.3 or 3.4 years. So if that number were the steady state number, we would level off at about 19,800.

Senator WEICKER. How much more would it cost to maintain the research grant base produced by 6,100 new grants each year, rather than 5,100 proposed in your budget submission?

Dr. WYNGAARDEN. The immediate additional cost in 1987 would be approximately $150 million at the average cost level assumed in the 1987 budget request.

Senator WEICKER. That is at the 6,100 level.

Dr. WYNGAARDEN. That is correct. The ultimate cost of a 6,100 base would be something on the order of 3.4 times that figure, with some escalation for inflation each year. It would be on the order of $500 to $600 million more.

Senator WEICKER. Over the 3-year period.

Dr. WYNGAARDEN. Over the 3-year period, yes. It would be approximately $150 million in 1987, $250 million in 1988, and $360 million in 1989 over what would be required to maintain the 18,000 total research project grant level.

STAFFING AT NIH

Senator WEICKER. The fiscal year 1986 Senate appropriations bill and the conference report mandated 13,507 full-time equivalent positions for the National Institutes of Health. I understand that OMB did not permit 13,507 full-time equivalent positions in 1986, and that you are requesting only 12,649 for fiscal year 1987.

How are you able to conduct your increased research efforts with a reduction in the number of employees, and by that I mean AIDS, and many other situations?

Dr. WYNGAARDEN. We have tightened up a good deal, Senator, and have reduced the number of employees in several categories. Of the 451 that we reduced between 1985 and 1986, about 200 were in scientific positions, mostly young scientists, and the rest are in support positions.

Senator WEICKER. How has that impacted on the research efforts?

Dr. WYNGAARDEN. It has reduced the efforts modestly. We still are, obviously, supporting the high priority research, and giving the most active programs favored treatment in this rearrangement.

Senator WEICKER. Even AIDS has been impacted somewhat?

Dr. WYNGAARDEN. This area is one that we protected to the extent that we could. While there has been no reduction in positions in the AIDS Program, we have not received necessary additional FTE's and have, therefore, reassigned staff from other research areas.

Senator WEICKER. This probably brings into sharper focus as much as anything can in the sense that the military build-up is predicated on the speculation that we might be in an armed conflict which would cost American lives. That is a speculation. I am not saying that it doesn't have a basis, but it is a speculation.

There is nothing speculative about a person who has AIDS. There is nothing speculative at all. It is about as sure a death as anything I have seen. I don't understand why there should be even one cut. I don't know why anybody should be grateful for the fact that it took the least cut. I don't understand that.

I just wish that I could get everybody in a different frame of mind that the disgrace is that we are not rolling forward on something such as that, as well as all of the other afflictions that are represented here.

In the budget priorities, 70 percent plus of all research support goes to the military function, $6 billion for health, and $43 billion in the military just on research. I just don't really understand how a Nation can have those proportions with any sense of pride.

AIDS CENTRALIZATION

Give me your opinion of the centralization project as far as AIDS is concerned.

Dr. WYNGAARDEN. It has some advantages of flexibility for the Department as a whole in providing the Assistant Secretary the option of moving those funds where they are most needed, together with the authority that he would have to move funds across appropriations in the new request.

The greater flexibility, I think, is responsive to the request of the Congress for greater coordination of the AIDS efforts. It gives greater visibility to the AIDS Program by coordinating all funding in the Assistant Secretary's office.

Senator WEICKER. From an administrative point of view, I probably would have no dispute with it. On the other hand, I think I am somewhat sensitive to the individualistic nature of your scientific compatriots. I wonder whether or not they don't do better work in the smaller units than being in a centralized format. What do you think?

Dr. WYNGAARDEN. The work is done in very small units, that is true. I think the individual scientist at the NIH and in the extramural world would be supported in much the same manner. I would assume that the funds for the continuation of the NIH programs would be allocated to us. There is no indication to the contrary.

Senator WEICKER. But, of course, it is by the person who holds the purse to give the focus as to the effort.

Dr. WYNGAARDEN. Yes.

Senator WEICKER. Are you personally satisfied with this new arrangement?

Let me say this right now. I am not being critical, but I am truly trying to find out here whether this is a good or bad thing. I was a little bit concerned, as were others, when we attended the conference on this item. In the last conference I think the issue was raised by several members where moneys were going to various entities, and where was the coordination in all of this.

Are you satisfied with this arrangement?

Dr. WYNGAARDEN. I think there is excellent coordination with whatever fiscal arrangement evolves. I don't see this as deterring the coordination of our efforts.

Senator WEICKER. This would encompass what, this $143 million, is that just NIH's portion of the AIDS Program?

Dr. WYNGAARDEN. Yes; the total amount is $213.2 million for all the agencies of the Department.

Senator WEICKER. What would be involved? We would have NIH. We would have the Centers for Disease Control. The Department of Agriculture, do they get in this thing?

Dr. WYNGAARDEN. No; this would be just the Public Health Service budget, including ADAMHA, NIH, CDC, FDA, and OASH. The FDA is funded through a different appropriation, so it is technically not included in the centralization.

Senator WEICKER. At this juncture, you don't feel—I realize that this hasn't taken place. Let me put it this way. Even though monetarily it hasn't taken place, administratively has it already taken place?

Dr. WYNGAARDEN. No; it has not.

Senator WEICKER. Would you feel free to discuss at any time with this committee if you felt that the scientific integrity of NIH were being harmed by such a centralization? Would you feel free to report that to us?

Dr. WYNGAARDEN. Yes.

Senator WEICKER. Then let's see what transpires.

BIOMEDICAL RESEARCH SUPPORT GRANTS

I understand the biomedical research support grant is a program that allows research institutions to strengthen their programs, their research programs. These funds can support pilot research projects, enable earlier recognition and support of young scientific talent, and provide funds to take immediate advantage of emerging opportunities.

You are proposing to save $58 million by stopping this program. How many institutions will this affect?

Dr. WYNGAARDEN. It is in the range of 576 institutions that receive some support from the BRSG Program.

Senator WEICKER. Why do you think the program ought to be stopped?

Dr. WYNGAARDEN. It has been a very valuable program, and it does provide flexible funds at the institutional level for pilot studies, starting young scientists, buying equipment, and things of that sort.

In the reduction of the budget, however, we had to select the highest priority component for support, and that remains the investigator-initiated research project grant. Consequently, the funds from the BRSG Program and some others had to be curtailed in order to support the basic research mission at adequate levels. It had a lower priority compared to other NIH programs at this time.

DEVELOPMENT OF BUDGET REQUEST

Senator WEICKER. Just to put it in its most simple terms, the 4.3 percent you assessed against every activity of NIH in the fiscal year 1986 budget.

Dr. WYNGAARDEN. Yes; the sequestration was applied against each appropriation, against each mechanism, and each special project that had a budgetary definition.

Senator WEICKER. In the preparation of your 1987 fiscal year budget, did you start from that reduced base, or did you add back in and then make your determination?

Dr. WYNGAARDEN. We started from the reduced base plus the postrescission request figure, and built the 1987 budget from that.

Senator WEICKER. So it is safe to say that the Gramm-Rudman cut on 1986 became permanent insofar as 1987 is concerned.

Dr. WYNGAARDEN. Yes.

Senator WEICKER. Are you familiar with what happened vis-a-vis the defense budget, do you know if that cut became permanent?

Dr. WYNGAARDEN. No; I don't.

Senator WEICKER. Would you care to guess?

Dr. WYNGAARDEN. I think you gave me the answer.

Senator WEICKER. It was put back in and then they started from there.

PROPOSED CAP ON INDIRECT COSTS

The Department of Health and Human Services research budget proposal assumes OMB's revision of circular 21 that would impose a cap on indirect administrative costs for universities of 20 percent in fiscal year 1987. I understand the national average for indirect administrative costs is 26 percent. How was the 20-percent cap for 1987 determined?

Dr. WYNGAARDEN. The cap is on a series of components of indirect costs, not on the total. These components currently average 26 percent of the direct costs figure. That is a national average, and there are many above and below it. The 20-percent figure was not selected by NIH. We made recommendations that are similar to this proposal. I think that the exact figure was chosen by others.

Senator WEICKER. Have you a national average that you understand to be the percentage insofar as administrative indirect costs are concerned?

Dr. WYNGAARDEN. The 26 percent is the national average for those categories over a 5-year period, representing approximately 56 percent of all indirect costs. This does not involve space costs, energy costs, and similar items. It is the categories that deal with departmental administration, research administration, general administration, and the administration of certain student activity programs. Those four categories together currently account for 26 percent of the direct costs figure, and the proposal is to reduce that in 1987 to 20 percent.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Jim, I have further questions for response to the record, and I would appreciate your answers to those and questions from other Senators.

I see my good friend, Senator Specter, arriving. Jim is just about to leave the witness stand. Is there anything that you would like to ask?

Senator SPECTER. No; thank you, Mr. Chairman. I would simply like to submit some questions for the record. I do not have any questions at this time.

I am sorry that I couldn't be here sooner, but I am chairing the juvenile justice hearing at the same time, but I did want to drop by.

Dr. WYNGAARDEN. Thank you, Senator; we will be happy to respond to those.

Senator WEICKER. Again, I thank you very much for your efforts, and you certainly enjoy the confidence of the chairman, and all of the committee. We have a very difficult month or so ahead of us in formulating the budget. What I really want to do from a timing point of view, I want to move fairly quickly on the NIH portion of the budget, and the reason that I want to do that is so that all of my colleagues will have a very complete picture as they make choices as between other activities of Government.

I don't want to wait until the end, until everybody has gotten their share, and then say, OK, you guys are going to get this. I think that it is terribly important that we develop the figures that are needed in this area early on. I am sure that if we do, in an intelligent way, that will help considerably in placing NIH in the proper perspective when it comes to priorities. We will be working probably much earlier than has been the case in the past in trying to develop the figures with you and your staff.

Dr. WYNGAARDEN. Thank you very much, Senator.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

RESEARCH PROJECT GRANTS

Question. The President's FY 1987 budget proposal would reduce the number of new grants for the National Institutes of Health by 600 in FY 1986 and by an additional 360 in FY 1987. This proposal would fund only 5,140 new grants and provide little more than a one-in-four chance for a research scientist to receive funding.

Yet last year you indicated that a maximum award rate of 45 percent to 50 percent would be necessary to maximize the research opportunities now present in what has been termed the golden age of biology. Is that still true?

Answer. In view of the expanding number of research opportunities before us, I believe that the optimal level of support would be to award 45 to 50 percent of all approved research project grant applications. This would ensure that at least a significant portion of potentially valuable science would receive support. However, within the levels available in this time of budget deficits, the NIH will continue to support a substantial portion of a high priority research.

Question. How many new grants would be required to achieve a 45-percent funding level in FY 1987?

Answer. We would need to support approximately 3,235 additional new and competing renewal awards for a total of 8,375 to reach a 45-percent funding level in FY 1987.

Question. How much would that cost?

Answer. The support of 8,375 new and competing renewal grants in FY 1987 at historical levels would require approximately $1.410 billion (for the first year only), an increase of $631 million over the request. The total three year cost of an additional 3,235 grants would exceed $1.7 billion.

Question. At the post-sequestered level of funding, NIH is now supporting 18,649 grants. This number includes both new and continuing grants. Is that correct?

Answer. Yes; excluding awards for the support of AIDS research, NIH would support a total of 18,649 research project grants in FY 1986 under post-sequestration. This number includes 12,576 noncompeting continuations and 6,073 new and competing renewal awards. Including AIDS, the number of research project grants is 18,776.

Question. How many grants would NIH support if we maintain 6,100 <u>new</u> grants every year?

Answer. As shown in the following table, the total number of research project grants would increase for the first 4 future years and would then stabilize at about 19,800.

	Fiscal Years					
	1986	1987	1988	1989	1990	1991
Noncompeting.....	12,676	13,334	13,860	14,060	13,700	13,700
Competing.....	6,100	6,100	6,100	6,100	6,100	6,100
Total.....	18,776	19,434	19,960	20,160	19,800	19,800

Question. How much more would it cost to maintain a research grant base produced by 6,100 new grants each year rather than the 5,100 proposed in your budget submission?

Answer. The President's budget proposes to fund a minimum of 18,000 total grants per year rather than proposing 5,100 new and competing renewal grants each year. Over a 5 year period this would average 5,600 new and competing grants per year. Under the total grant concept the mix between new and competing, and noncompeting would vary yearly, with between 5,100 and 6,400 new and competing grants funded in any given year.

The following table compares the estimated cost to maintain a research base produced by supporting 6,100 new and competing renewal awards each year and the estimated cost to maintain a total research project grants level of 18,000. Assumptions made in the estimates are that: the 1986 column represents the pre-sequestration appropriation level; the 1987 column represents the estimated full costs adjusted for historical negotiations; and 1988 through 1991 include average cost increases of 6.5 percent for noncompeting continuations, 4.0 percent for administrative supplements, and 6.0 percent for competing awards.

(Dollars in Millions)

	Fiscal Years					
	1986	1987	1988	1989	1990	1991
Estimated cost to maintain 6,100 competing awards each yr.....	$3,053	$3,422	$3,737	$4,014	$4,190	$4,455
Estimated cost to maintain 18,000 total awds. per yr.	3,053	3,173	3,370	3,586	3,812	4,111
Addit. amt. needed.....	0	249	367	428	378	344

FTE REDUCTION AT NIH

Question. The FY 1986 Senate appropriations bill and the conference report mandated 13,507 full-time equivalent positions (FTEs)

for the National Institutes of Health. I understand that OMB did not permit 13,507 FTEs in 1986, and that you are requesting only 12,649 FTEs for FY 1987. How are you able to conduct your increased research effort for AIDS with a reduction in the number of employees?

Answer. The OMB does not assign NIH a specific FTE number. This number is allocated to NIH by the Department. The NIH has made, and will continue to make, every effort to minimize the adverse impact of FTE reductions on the science conducted and supported by the agency in all the areas within its purview, as well as on patient care activities. Because of the high priority assigned to the AIDS effort, positions in this area have been excluded from reductions.

Question. Have any research programs lost personnel due to this reduction in FTEs?

Answer. The FTE reductions have resulted in fewer personnel in several research programs at NIH. Current estimates indicate that the proposed reduction would come from the following areas: 208 FTEs from the intramural research program; 60 FTEs from administrative staff and from staff associated with managing the extramural program; 79 FTEs from central services such as police and fire protection, procurement, and maintenance services; and 104 FTEs from Cancer Control, the National Library of Medicine, and the Office of the Director. As stated earlier, however, we are continuing our effort to minimize the impact on high priority programs and on patient care activities.

Question. How many FTE positions were requested by the Directors of the research Institutes and Divisions for FY 1987?

Answer. In their budget submissions to the NIH, the Bureaus, Institutes, and Divisions requested 14,023 FTEs for FY 1987.

Question. What was your request to the Department of Health and Human Services for FY 1987?

Answer. The NIH request to the Department included 13,534 FTEs for FY 1987.

CLINICAL TRIALS

Question. The ability of the National Institutes of Health to conduct clinical trials of new research funding has received increased support over the past 3 years. We have been told of the great many advances in our biomedical knowledge. Given the fact that the clinical trial is the method by which these discoveries are brought to the bedside, are we supporting enough clinical trials?

Answer. With clinical trials, as with all research projects, NIH must select the most meritorious from among many competing proposals, not all of which can, or should, be supported. Those clinical trials most worthy of NIH's support are those which are technically, methodologically, and ethically sound, and which fulfill one or more of the following criteria:

- o The trial holds promise for making a substantial contribution to the health of the American people.

- o It may well complement basic laboratory and animal research in increasing understanding of the basic biology of the target disease.

- o There is a distinct possibility that its execution will contribute to future improvements in the design, analysis, and interpretation of clinical trials in general.

Question. Can you provide a list of the trials that should begin this year and identify the one that won't because of budget restraints?

Answer. The following is a list, by Institute, of the major new clinical trials that will begin in FY 1987, followed by a list of the ones that would be ready to begin if funds were available.

MAJOR NEW CLINICAL TRIALS TO BE FUNDED AT 1987 REQUEST LEVEL
(Dollars in Thousands)

	First Year Cost	Estimated Total Cost
NCI:		
Comparison of bone marrow transplantation with chemotherapy for advanced stage neuroblastoma	$500	$1,500
Clinical trials using angiogenesis inhibitors	250	750
National collaborative diagnostic trials for staging and monitoring carcinoma of the prostate and lung	600	2,400
Phase III clinical trials in intraoperative radiotherapy for intra-abdominal malignancies	300	1,500
Phase II studies of adoptive immunotherapy of cancer with autologous LAK cells and IL-2	3,600	4,680
Treatment/imaging of lung cancer with a monoclonal antobody directed against bombesin/gastrin releasing hormone	488	1,464
Adoptive immunotherapy utilizing LAK cells and IL-2 administered intraperitoneally for patients with ovarian and colorectal cancer	172	516
Subtotal, NCI	5,910	12,810
NICHD:		
Studies on new long-acting injectable projestins	250	850
Comparison of effects of oral contraceptive use on physiological indicators of cardiovascular disease risk	200	1,200
Subtotal, NICHD	450	2,050
TOTAL, NIH	6,360	14,860

MAJOR NEW CLINICAL TRIALS READY TO BEGIN IN 1987
IF FUNDS WERE AVAILABLE
(Dollars in Thousands)

	First Year Cost	Estimated Total Cost
NCI:		
Biochemical modulation of chemotherapeutic agents in colorectal, breast, stomach, and head and neck cancers	$ 750	$2,200
Phase II/III clinical trials using hyperthermia in anatomical sites	600	1,800
Phase I/II trials of additional biological response modifiers	4,000	6,000
Treatment of resectable colorectal hepatic metastases with surgery followed by LAK cells/IL-2 adjuvant immunotherapy	575	1,725
Phase III studies of adoptive immunotherapy of cancer with autologous LAK cells and IL-2	20,000	40,000 1/
Comparison of post operative radiotherapy and adjuvant chemotherapy with chemotherapy, in children with medulloblastoma	100	300
Phase I/II clinical trials of biological response modifiers	2,000	2,500
Treatment of carcinoma of the bladder with hematoporphrin with photoradiation therapy	70	210
Use of TNF in patients with metastatic cancer who have failed conventional therapy	1,150	3,450
Study of radiolabeled monoclonal antibodies to detect sites of Hodgkin's disease involvement	182	546
Subtotal, NCI	29,427	58,731
NHLBI:		
Bypass angioplasty revascularization investigation	1,000	28,600
Dietary intervention in children	700	9,255
Coronary artery bypass graft study	850	29,500
Postmenopausal estrogen and coronary heart disease risk	4,000	12,700
Treatment of pulmonary embolism with tPA	1,000	10,000
Continous positive alveolar pressure treatment of sleep apneas	800	4,000
Penicillin prophylaxis in sickle cell disease	900	1,800
Post-transfusion Non-A, Non-B hepatitis study	1,000	3,215
Deep vein thrombosis diagnosis and treatment	600	10,800
Subtotal, NHLBI	10,850	109,870

1/ Tentative estimate; final cost to be determined when required duration of trial is known.

	First Year Cost	Estimated Total Cost
NIDR:		
Diabetes Control and Complications Trial (DCCT), oral complications.....	$ 150	$ 300
Clinical evaluations of the relative efficacy and safety of intravenous premedication in dental outpatients.....	225	425
Subtotal, NIDR.....	375	725
NIADDK:		
Treatment of short stature with human growth hormone.....	420	1,400
Nonsurgical (balloons) reduction of stomach capacity in the treatment of morbid obesity.....	212	464
Postoperative decompression feeding trial..	4,785	25,500
Kidney transplantation in children with end-stage renal disease.....	250	1,000
Expanded nephrologic component of the Diabetes Control and Complications Trial.....	480	6,650
Controlled clinical trial of hematin therapy for acute prophyric attacks.....	450	2,500
Subtotal, NIDDKD.....	6,597	37,514
NINCDS:		
Stroke prevention medical surgical carotid stenosis study in asymptomatic patients.....	3,019	27,394
Stroke prevention by carotid endarterectomy in symptomatic patients.....	4,176	29,177
Study of cyclosporin A for the management of autoimmune disorders.....	500	1,575
Monoclonal antibody treatment of multiple sclerosis.....	500	1,575
Study of monoamine oxidase inhibitors for the treatment of Parkinson's disease.....	2,000	7,000
Study of orphan products for the treatment of rare movement disorders such as Tourette's syndrome.....	1,200	3,600
Copolymer 1 in the treatment of multiple sclerosis.....	2,250	6,750
Efficacy of new antiepileptic drugs in patients with complex partial seizures (two trials).....	500	1,500
Subtotal, NINCDS.....	14,145	78,571
NIAID:		
Monoclonal antibodies in bone marrow transplantation.....	1,200	4,800
Efficacy trial for rDNA hepatitis B vaccines.....	150	600
DHPG prophylaxis of cytomegalovirus in bone marrow transplant patients.....	450	900
Expanded phase I and II trials of antimalarial vaccines.....	60	135

NIAID: (cont.)	First Year Cost	Estimated Total Cost
Efficacy trial for live, attenuated hepatitis A virus vaccine	$ 150	$ 450
Study of different regimens of therapy for systemic candidiasis	300	1,691
Subtotal, NIAID	2,310	8,576
NICHD:		
Effects of growth hormone releasing factors	500	2,000
Nutrition, other factors, and the outcome of pregnancy	150	600
Factors influencing breastfeeding	150	600
Mental Retardation Research Centers network of clinical trials	1,200	6,000
Safety and efficacy of pertussis vaccine	2,200	8,400
Safety and efficacy of *Hemophilus influenzae* vaccine	500	1,500
Clinical studies with a long-acting spermicidal formulation	150	350
Tests of the use of medications to treat various maternal diseases and the safety and efficacy of various therapeutic agents to stop premature labor	500	2,500
Examination of current treatments in long-term management of bronchiopulmonary dysplasia, and the use of anticonvulsants in the treatment of neonatal seizures	500	2,500
Subtotal, NICHD	5,850	24,450
NEI:		
Central retinal vein occlusion study	1,000	5,000
Treatment of optic neuropathy with steroids	1,500	8,000
Surgical reattachment of the retina in advanced severe retinopathy of prematurity	3,000	12,000
Evaluations of epikeratophakia and keratoprostheses treatment for corneal disorders	1,500	7,000
Surgical vs. laser management of advanced glaucoma	1,000	5,000
Subtotal, NEI	8,000	37,000
NIAMSD:		
Epidermolysis bullosa: efficacy of dilantin and treatment of esophageal strictures	500	2,500
Efficacy of 13-cis retinoic acid in treating keratinizing disorders	1,000	3,000
Subtotal, NIAMSD	1,500	5,500
TOTAL, NIH	79,054	360,937

AIDS: CENTRALIZATION OF FUNDS

Question. Funding for AIDS research has been centralized under the Office of the Assistant Secretary for Health (OASH) in FY 1987. Did this enhance your ability to get OMB and HHS approval for your AIDS research funding proposals?

Answer. The FY 1987 budget request for the NIH AIDS research program was developed in September 1985, thus pre-dating the proposed centralization of funding within the OASH. I do not believe the centralization affected getting OMB or HHS approval of AIDS funding.

Question. The placement of funds in OASH adds another layer or two of bureaucracy between these research funds and the research scientist. How much discretion will the individual institution have in determining program priorities for AIDS research?

Answer. The Institutes will continue to determine their individual priorities for AIDS research. The availability of funding from the OASH appropriation will depend on the priorities established by the Assistant Secretary for Health and by the PHS AIDS Coordinator, in consultation with the various PHS AIDS program managers and scientists.

Question. Will Institute Directors have to justify their program to a central coordinating body in the Office of the Assistant Secretary for Health?

Answer. Through the normal consultative process, the Assistant Secretary will allocate funds according to scientific promise, public health need, and research opportunity.

Question. Will grant applications have to go through additional levels of review to qualify for funding?

Answer. Individual grant applications would not be subject to additional levels of review.

Question. In your opinion, how will this centralization affect the AIDS research program at NIH?

Answer. The Department believes that centralization of AIDS funding would result in greater visibility of the Government's efforts in this area, broader flexibility in responding to needs when and where they occur, and more control over funding during a time of fiscal austerity.

AIDS: FUNDING LEVELS

Question. I note that you are requesting $144 million for research into AIDS for FY 1987. What was the total request of the Institute Directors to your office for FY 1987, and what was your request to the Department?

Answer. The overall FY 1987 funding request of $143,868,000 was developed in September 1985 as an adjunct to a proposed budget amendment for 1986. The currently anticipated 1987 reimbursement to NIH is $142,990,000.

Question. Given the long lead time necessary in the development of your budget, is $144 million for AIDS research still adequate, or has additional funding become necessary?

Answer. The current estimate of $142,990,000 would provide support for most on-going efforts in AIDS research as well as a modest provision for new programs. The Institutes have tentatively identified additional requirements which are currently being reviewed.

AIDS: VACCINE DEVELOPMENT

Question. Last year during this Subcommittee's deliberations on AIDS, it was determined that the National Cancer Institute and the National Institute of Allergy and Infectious Diseases should receive an additional $14 million to intensify research on a vaccine for this terrible disease. You are now asking for a rescission of the $14 million, and I am told that NIH plans to spend only $10 million on vaccine development in FY 1986. In your professional judgment, given the urgency of the situation, how much funding should be available to produce a maximum research effort to find a vaccine?

Answer. I would first like to clarify a few points about the proposed rescission. Within the FY 1986 appropriation, the Institutes had identified a total of $70.7 million for AIDS research; the appropriation bill also contained a provision for $70 million in the appropriation of the Office of the Director for allocation to the Institutes in response to emerging opportunities. The proposed rescission affects the OD appropriation only, reducing it by $13.9 million.

You are correct that approximately $10 million will be available for vaccine development within the FY 1986 revised request. In my professional judgment, as well as that of the members of the NIH AIDS Executive Committee, an additional $4.5 million would produce a maximum effort in AIDS vaccine research for the remainder of this fiscal year.

BUDGET PRIORITIES AND RESEARCH

Question. The budgetary priorities of this Administration for the support of research have not been favorable to the National Institutes of Health or the Alcohol, Drug Abuse, and Mental Health Administration. (Seventy plus percent of all research support goes to military functions; $6 billion for health vs. $43 plus billion in military.)

The number of new grants has become a rallying point in my battle with the Administration and has resulted in an increase in the number of these grants by over 1,000 in the past few years. I am concerned, however, that other research and support mechanisms at NIH may not have received the attention needed to allow them to function at necessary levels. Can you comment on this concern and identify specific areas that perhaps should receive more attention?

Answer. While the support of investigator-initiated research has been our highest priority and has grown faster than the other mechanisms, we have also made every effort to maintain a balanced program of research activities.

Because of the pressing need to reduce the Federal deficit, the FY 1986 current estimate and FY 1987 request include reductions from FY 1985 in all NIH funding mechanisms.

FOREIGN COMPETITION

Question. I have been reading that countries like Japan, Germany, and France have begun to increase the resources available to their biomedical research effort. Are we beginning to lose our competitive position in various areas of biomedical research and technology?

Answer. We are beginning to see an increase in resources being devoted to biomedical research by such industrialized countries as Japan, Germany, and France. In 1983, the Office of Technology Assessment published a report on the competitive position of the United States with respect to Japan and four European countries: West Germany, the United Kingdom, Switzerland, and France. The report stated that, even though the United States was currently the world leader in the basic sciences and commercial development of new technology, continuation of this preeminence was not guaranteed. Given that other countries are increasing their resources devoted to biomedical research or have national policies for the active promotion of biotechnology, the U.S. position is no longer assured.

Japan and Germany are especially competitive. Japan has a steady increase in investment of resources, particularly in biotechnology, and Germany in investing more money to bring U.S. scientists to its laboratories than we are to send U.S. scientists to Germany. Recently, the White House Office of Science and Technology Policy formed a Committee on International Science, Engineering, and Technology, which will study this and related questions. The NIH will be participating along with other Federal agencies and hopes to gain a clearer picture of where the Unites States stands and the directions it should take in this regard.

Finally, it should be noted that we believe that international competition in the biomedical sciences should be viewed as stimulating advances in knowledge that can benefit all countries.

Question. If this is true, what effect will this have on the health of our citizens in future years and on the health of our country's economy?

Answer. The increase in resources for biomedical research by other countries may well have a significant impact upon the health of our citizens in such areas as vaccine development and basic knowledge regarding certain pandemics such as AIDS. In terms of health, advantages from research--wherever derived--should benefit everyone, and international competition has no adverse impact on the health of our citizens. We need to keep our international linkages strong to derive maximum health benefit from such "competition."

On the other hand, commercialization of biotechnologies and stronger foreign competition could have a negative economic impact on related U.S. industry. In particular, the Nation's economy could be affected if U.S. firms are not able to retain their lead, world-

wide, with the consequence that products may become more costly to produce, thus increasing costs related to disease prevention and treatment.

Question. In your professional judgment, what programs would you expand or initiate to avoid what may become a national catastrophe?

Answer. We must remove any artificial barriers to research collaboration across geographic boundaries and encourage our scientists to go abroad to work collaboratively in laboratories that are in the forefront of biomedical sciences. Thus, Federal programs offering opportunities to U.S. scientists to collaborate with foreign scientists must be expanded and made more attractive. We are addressing this matter by developing a research fellowship program that will enable junior U.S. scientists to work in foreign laboratories. We also want to afford opportunities for senior scientists to come to the United States in order to share their knowledge with U.S. investigators. There are excellent research centers abroad--notably in Japan, Germany and France--engaged in high-quality research about which we know too little. Such exchanges will enable us to maintain our lead in biomedical research.

Additionally, increased emphasis can be placed on selected domestic research programs that have the greatest potential to provide improved strategies for disease prevention and treatment.

INDIRECT COSTS

Question. The Department of Health and Human Services research budget proposal assumes OMB's revision of Circular 21 that would impose a cap on indirect administrative costs for universities at 20 percent for FY 1987. I understand that the national average for these indirect costs is 26 percent. How was the 20-percent cap in FY 1987 determined?

Answer. The reduction in the allowance for administrative overhead from 26 percent in FY 1986 to 20 percent in FY 1987 is based on a compromise from the Office of the Inspector General's recommendation to reduce the departmental administration component of indirect costs by 8 percentage points, from the current level of 15 percent of modified total direct cost to 7 percent. It was the judgment of the Inspector General that, although departmental administration represents the fastest growing portion of indirect costs, this activity is not well-documented and provides little or no benefits to research.

Question. I understand all universities do not account for their indirect costs in the same way and that capping these costs will affect some institutions disproportionately. Do you have any evidence that this is not the case? How do you plan to deal with this problem?

Answer. Each institution accounts for its indirect costs differently. Two institutions with the same indirect cost rate could vary in the proportion of each component making up indirect costs. Implementation of a cap on indirect administrative costs would, in

fact, affect each institution differently depending on its proportion of administrative costs, as a component of indirect costs, to direct costs.

Though this policy will affect some institutions disproportionately, we believe a uniform policy of reimbursing for costs associated with non-research administrative overhead functions is the most appropriate way to deal with these very hard-to-measure costs.

Question. Why has your Department adopted this provision for FY 1987 while all other agencies have chosen to delay implementation for one year as authorized in OMB's proposal?

Answer. The Department of Health and Human Services has proposed an early implementation date for this policy as a means of freeing up additional resources for biomedical research.

GRANT FUNDING LEVELS

Question. In the FY 1986 budget for the National Institutes of Health, Congress provided enough funds to pay about 95 percent of the projected full cost of a research grant. The sequestering mandated by the Gramm-Rudman-Hollings Act reduced that 95 percent even further. Now, I understand that up to a point any program can absorb some reduction in funding. Can you tell us on the average at what point the reduction from recommended funding levels becomes critical and give us a few examples of how important research can be hurt?

Answer. It is important to recognize that the NIH grants peer review system provides a systematic, thorough, and expert assessment of the appropriate award level for each grant. Negotiations with pending awardees provide opportunity to cut slight amounts (2 to 5 percent) from actual awards in order to correct for minor adjustments in available and required resources to perform the work.

Cuts of about 5 to 10 percent, however, would delay progress by causing some cut-backs in support personnel, postponing various equipment and supply purchases, canceling travel to meetings, and decreasing numbers of human subjects or experimental animals that could be handled.

We believe that decreasing grant budgets by more than 10 percent from recommended levels could lead to severe disruptions in the investigators' ability to perform the approved research. While investigators with larger grants, such as program and center projects, might be able to accomplish essential functions by rebudgeting within available funds, most investigators would need to reduce important support and professional staffs and to forego expenditures for some otherwise essential equipment, supplies, travel, and patient and animal work. These limitations could disrupt the grantees' ability to accomplish research goals and thus impede scientific progress of the projects. While these sequelae could be minimized by not negotiating so drastically on individual grants, the alternative choice of funding fewer grants in the aggregate could similarly limit advances in biomedical sciences and knowledge.

CONSTRUCTION AND REHABILITATION

Question. Dr. Wyngaarden, you and your colleagues have testified several times about the necessity of maintaining a modern physical plant for the extramural program. Several studies have indicated that $20 to $40 billion dollars will be necessary to construct and renovate laboratory facilities in the universities across the country. Where do you propose this amount of money will come from if the Federal Government doesn't play its part?

Answer. The figures cited have been based almost entirely on subjective estimates. Verifiable evidence of the nature and extent of the national need is simply not available. We do know, however, that in 1984 the Federal Government was directly financing only 7 to 8 percent of academic research facilities construction and renovation activity, whereas in 1975 the Federal share was 25 percent. However, through the indirect cost mechanism Federal payments for buildings' use and depreciation represent a source of funds for university capital investment. Correspondingly, capital investments in academic research facilities dropped 44 percent between 1975 and 1982. During the past decade alternative sources of funding have not been able to fill the gap left by the decrease in Federal support, and there is little reason to expect that these circumstances will change in the near future.

Limited available evidence indicates that State and local governments have provided nearly half the funds that were used by academic institutions for research facilities in the period 1980-85. Separately budgeted research funds provided another 30 percent. Presumably the latter includes some indirect cost recovery.

The proportion of dollars awarded for indirect costs associated with competing research project grants has increased 63.6 percent in the last 5 years. Indirect costs now account for 32.5 percent of the average total cost of a research grant award, and resistance to further increases is great. Included in indirect costs are the costs of interest on debts, and depreciation and use allowances.

Question. What will be the long-term impact if the facilities are allowed to become obsolete and fall into disrepair?

Answer. Facilities that are out of date and in poor repair interfere with both the quality and quantity of research that can be done and contribute to increased risks to the safety of investigators.

Question. Can we look forward to the same loss of leadership in biomedical research as experienced by the American automobile and steel industries over the past two decades?

Answer. The position of leadership in biomedical research that the United States currently enjoys is largely the result of over four decades of sustained support for research and research training. Through that effort, there was gradually established a network of trained investigators, training sites, and well-equipped laboratories and clinics devoted to the pursuit of biomedical research. It is that system of research which today is widely acclaimed as second to none.

While there is no single indicator of scientific prominence, a measure of this quality is provided by the number of Nobel prizes and other prestigious awards received, the volume and quality of scientific papers published in leading journals, selection to serve on important international scientific bodies, membership in scholarly societies, and the ability to attract outstanding students for post-doctoral training. By all these standards, there is every indication that the U.S. position of leadership in biomedical research is undisputed.

Although I believe the United States will continue to maintain its preeminence in biomedical research, there is no room for complacency. Recently, for instance, we have witnessed the appearance of stresses and strains in the U.S. biomedical research enterprise as a result of efforts to maintain the momentum of scientific progress during periods of prolonged fiscal constraint. These strains are evident in the declining proportion of successful applicants for research grants who are able to obtain funding from the NIH and in the steady deterioration of the physical environment in which research is conducted. In addition, several countries have developed their scientific infrastructures to the point where they can now mount serious challenges to the U.S. supremacy in biomedical research.

Leadership in any endeavor is a fragile commodity that requires a constant effort to sustain. Just as the leadership position of the United States in biomedical research today is the result of efforts made and resources expended decades earlier, so will the position of this country in the next decade, and beyond, depend upon decisions and commitments made today. I feel confident that the depth and resiliency of the U.S. research system, coupled with the Nation's commitment to biomedical research, will permit us to continue the leadership role we have so long enjoyed.

Question. How much funding should be made available for construction and renovation of the extramural facilities in FY 1987?

Answer. In the FY 1985 NIH appropriation, a total of $13.1 million was provided to the National Cancer Institute, the National Heart, Lung, and Blood Institute, and the National Eye Institute to help address the growing concerns over the obsolescence of research facilities in the Nation's research universities. In FY 1987, the NIH budget proposes elimination of the extramural construction program. Termination of this program in FY 1987 may cause the postponement of some research facilities construction, but constrained resources have required many difficult funding decisions.

QUALITY OF SCIENTIFIC ACHIEVEMENT

Question. At yesterday's budget hearing, the Secretary of Health and Human Services, Dr. Bowen, indicated that the FY 1987 budget would not compromise the quality of scientific achievement at the National Institutes of Health. Yet this budget would support only 28 percent of peer-reviewed grant proposals. In your professional judgment, does the level of funding compromise the quality of scientific achievement?

Answer. The FY 1987 request will support approximately 18,000 research project grants.

Because of budget constraints, the funding level and number of investigator-initiated research project grants in the FY 1987 request is admittedly less than optimal. However, the NIH can maintain its progress in biomedical research without compromising the quality of its scientific achievements.

Question. At what percentage will we begin to compromise?

Answer. We would not sacrifice the quality of the science that we are supporting at any level. A reduced award rate will, however, limit the number of research opportunities that can be pursued.

GRAMM-RUDMAN

Question. NIH has been required to absorb the 4.3-percent ($230 million) Gramm-Rudman cut in FY 1986 by budget mechanism. Does this present problems for the research Institutes or does the lack of flexibility interfere with the Institutes' mission?

Answer. As a result of the Balanced Budget and Emergency Deficit Control Act, the FY 1986 appropriated level for NIH has been reduced by about $236 million. The reduction was applied evenly across all mechanisms. We are currently reviewing our programs to see if we will need to request shifts in funds.

Question. How much direction and flexibility should the Director of a research Institute have in order to minimize the indiscriminate impact of across-the-board cuts? If you had the flexibility to allocate the reductions among your programs in another way, would you shift these funds? Please explain why your choice of distribution would produce better management results.

Answer. We are looking at the need to reprogram and will request shifts in these funds if appropriate.

PREVENTION RESEARCH

Question. The Health Research Extension Act of 1985 (P.L. 88-158) establishes Associate Directors for Prevention in only three Institutes (NCI, NHLBI, and NICHD). Do you see these Institutes as having a greater need to focus on prevention research?

Answer. The prevention of disease has been a primary goal for all the Institutes at NIH for some time. The three NIH components that are establishing positions for Associate Directors in this area understandably have strong visibility in prevention because of significant public interest; additionally, all three have longstanding programs aimed at prevention of disease, disorders, and disabilities.

Question. Might the other categorical research Institutes benefit from the establishment of Associate Directors for Prevention?

Answer. At this time, I believe that the prevention area is adequately managed and supported. It is important to note that, in response to a requirement in the Health Research Extension Act of

1985, the NIH has recently established the position of Associate Director for Prevention within the Office of the Director, NIH. The new Associate Director will have responsibility for promotion and coordination of the disease prevention research programs of the NIH Institutes.

The Office of Disease Prevention will be responsibile for providing advice regarding disease prevention to the Director, NIH, and overall guidance to the research institutes on biomedical programs that seek to improve the Nation's health through research, research training, and the exchange of knowledge as these activities relate to disease prevention. The Office will be responsible for coordination of components and between the NIH and other agencies of the Department, and with other public and private entities. The Office will provide leadership in planning, developing, and reviewing policies and guidelines for activities of the disease prevention programs of the NIH.

RESEARCH PRIORITIES

Question. To what degree does public pressure influence the way in which priorities for biomedical research are set?

Answer. It is difficult to assess the degree to which any one factor influences the way in which priorities for biomedical research are set, since the final allocation of resources is the result of a complex inteplay of many factors. In setting overall priorities, the NIH must meld scientific opportunity with broader policy considerations. To accomplish this, the NIH weighs several factors: 1) the public health importance of a disease (as measured by mortality and morbidity rates and estimates of the social and economic burden of disease); 2) the state of knowledge in areas of science underlying the various diseases; 3) the availability of trained manpower, facilities, and equipment to mount major initiatives; 4) the views of various constituency groups; and 5) the thrust of congressional mandates and special directives.

The NIH gives consideration to the concerns and wishes of the public, expressed directly and through congressional and Executive Branch actions. For instance, authorizing legislation, mandates, directives, and appropriations all influence our research planning and the conduct of our programs. A few examples of congressional and Administration actions that set our course are: concern for providing greater support to broad areas of research; mandates and directives to allocate a proportion of resources to a particular disease area; directions for long-range plans; changes in research training legislation; proposals for small business set-asides; and establishment of commissions and task forces to provide advice in guiding resource allocations.

Additionally, an important part of the priority-setting process involves the views of professional societies and voluntary health organizations, the biomedical research community, and the general public. These views are sought through a variety of means, ranging from structured activities such as National Advisory Councils, special groups, or task forces or commissions to consider specific

research areas or health problems, to less structured individual interaction with representatives of such groups.

Question. Has public pressure affected the balance between clinical and basic research?

Answer. The process by which funds are allocated to basic and clinical research is part of the broader priority-setting process at NIH, which involves the interaction of: 1) the peer review system to determine scientific merit of investigator-initiated research project grant proposals; 2) the advice of national advisory councils and their role in program planning; 3) the results of assessments of the public health importance of various diseases; 4) the state of knowledge in relevant areas of science; and 5) the views and concerns of the public as expressed through the Congress and by representatives of various constituency groups.

I should note that the NIH does not make deliberate funding decisions to achieve some arbitrary "balance" between basic and clinical research. We view such research as part of a continuum. Consequently, the distribution of funds along this research continuum, while influenced by all the social, political, and economic factors described above, is most strongly determined by the state of science as perceived by the scientific community and reflected in the distribution of research grant applications.

ISSUES

Question. Please summarize the most important issues confronting the biomedical research establishment in an environment of substantial cutbacks in the Federal budget in coming years.

Answer. An overriding concern during a protracted period of fiscal austerity is to maintain the stability and integrity of the research system that has been painstakingly developed over many years, and to sustain the momentum of scientific progress during what is clearly a period of unprecedented scientific opportunities. To accomplish these complementary goals, it is essential to provide a steady and predictable level of funding for basic biomedical research through the support of investigator-initiated research project grants.

In pursuing this goal, however, we must guard against the danger of creating serious program imbalances through neglect of other important program components. We must, for instance, provide funds necessary to support a relatively constant number of trainees to assure a cadre of new scientists to meet our national research needs; maintain support for research centers, many of which combine basic research with clinical application; continue clinical trials to provide evidence of the safety and efficacy of new medical interventions; maintain the NIH intramural research program, which performs laboratory and clinical research across the full spectrum of disease areas; and strengthen technology transfer involving the acquisition, storage, and dissemination of information needed in biomedical research, health professional education, and the delivery of health care.

Finally, no assessment of issues in science policy would be complete without addressing the growing need to find appropriate ways to strengthen and upgrade the research infrastructure. Over the past decade, increasing concern over the deterioration of the research environment has been widely expressed. The most prominent concerns are for the growing shortages and obsolescence of research instrumentation and the physical deterioration of laboratories, animal buildings, and other research facilities.

RESEARCH PROJECT GRANTS

Question. How many competing research project grants have you awarded so far in FY 1986?

Answer. As of February 28, 1986, the NIH had awarded 1,483 new and competing renewal research project grants.

Question. Did you attempt to hold down the average costs of grants that were awarded early in the fiscal year so as to moderate the impact of budget cuts on grantees who would be receiving their awards in the latter half of FY 1986?

Answer. Because of budget uncertanties, the Institutes have proceeded cautiously in the award of grants.

EXTRAMURAL FUNDS

Question. What proportion of NIH extramural funds goes to investigators outside the United States?

Answer. Approximately 0.5 percent of the total dollars awarded for research project grants in FY 1985 supported investigators outside the United States.

Question. Please provide figures for competing and noncompeting research project grants in both dollars and numbers of grants.

Answer. In FY 1985, 202 awards were made to investigators outside the United States; the total cost was $14,102,000. Of this amount, $5,436,000 supported 71 new and competing renewal awards, and $8,666,000 supported 131 noncompeting continuation awards.

TUBEROUS SCLEROSIS

Question. The Committee has received several dozen letters concerning a disease called tuberous sclerosis. Please provide the Committee with a brief description of tuberous sclerosis, how much is understood about the disease, and how much is being spent on research for this disease.

Answer. Tuberous sclerosis (TS) is a genetic disorder that causes a variety of neurological and physical disturbances, including seizures, mental retardation, and tumors of the brain or other organs. The disorder can also cause: white spots on the skin of the trunk and limbs; physical handicaps such as motor difficulties; delayed development of speech, language, and learning skills; and characteristic skin rash over the cheeks below the eyes. Patients

may have one or more of these conditions in varying degrees of severity. In its most devastating form, TS renders the patient completely helpless and dependent. The disease is inherited in autosomal dominant genetic fashion so that each child of an affected parent has a 50-percent chance of developing TS. Some cases, however, arise from spontaneous mutation, or change, of the gene. The disease affects both males and females, in all races.

Tuberous sclerosis results from disruption of normal development of the central nervous system. It is likely that the main site of the abnormality is an embryonic structure known as the neural crest from which cells migrate to various parts of the body and take part in the formation of certain tissues and organs. White spots are of importance for early diagnosis since they are present in 90 percent of affected infants. Manifestation of the disorder varies widely. New neuroimaging technologies are helping to identify TS lesions in the brain and other organs early in the course of the disorder. Although the disorder is transmitted genetically, the exact cause of the lesions associated with TS is unknown.

In FY 1985, the National Institute of Neurological and Communicative Disorders and Stroke supported TS-related research at a total cost of $19.5 million. The FY 1986 and 1987 estimates are $19.9 million and $19.7 million, respectively.

BIOMEDICAL ETHICS BOARD

Question. The newly authorized congressional Biomedical Ethics Board is directed by P.L. 99-158 to study the ethical implications of human genetic engineering. How might this work relate to the ethical guidelines for human genetic engineering as proposed by the Recombinant DNA Advisory Committee?

Answer. The Biomedical Ethics Board is directed to "study and report to the Congress on a continuing basis on the ethical issues arising from the delivery of health care and biomedical and behavioral research, including the protection of human subjects of such research and developments in genetic engineering (including activities in recombinant DNA technology) which have implications for human genetic engineering."

The NIH Recombinant DNA Advisory Committee (RAC) will be reviewing individual proposed human gene therapy protocols on a case-by-case basis as stipulated by Section III-A-4 of the "NIH Guidelines for Research Involving Recombinant DNA Molecules." The RAC has developed a document, Points to Consider in the Design and Submission of Human Somatic Cell Gene Therapy Protocols, to assist investigators in preparing proposals for submissions to the RAC. We anticipate that the Biomedical Ethics Board will take this document into consideration and will closely follow future RAC deliberations on this issue.

Question. Is the RAC scheduled to establish a formal liaison with the congressional Biomedical Ethics Board?

Answer. Under P.L. 99-158, the Biomedical Ethics Board is directed to appoint a Biomedical Ethics Advisory Committee to conduct

the studies and make the reports required by the Act. NIH staff intends to invite a member of the Biomedical Ethics Advisory Committee, and/or appropriate staff, to serve as liaison to the RAC. In turn, NIH hopes that a RAC member and/or NIH person will be invited to serve as NIH liaison to the Biomedical Ethics Advisory Committee.

VACCINE DEVELOPMENT

Question. What are your priorities for the development of a new pertussis vaccine?

Answer. The development and evaluation of new, improved pertussis vaccines is a major priority of NIH. The National Institute of Allergy and Infectious Diseases (NIAID) and the National Institute of Child Health and Human Development (NICHD) currently support research aimed at accelerating the development and use of new pertussis vaccines.

Support for pertussis research at NIH occurs through several different mechanisms such as grants, fellowships, contracts, and intramural research. Much of the basic research associated with pertussis involves attempts to better understand the pathogenesis of disease, determine host-bacteria interactions, and study the immunochemistry of pertussis antigens. A better understanding of these areas will contribute significantly to vaccine development.

The NIAID currently is funding a contract to expedite the development of an acellular pertussis vaccine and also supports four vaccine evaluation units for the clinical testing of candidate vaccines from various sources. Scientists at NIAID's Rocky Mountain Laboratories are also involved in the development of a "third generation" pertussis vaccine using recombinant DNA technology. The most significant effort to date is the conduct of an efficacy trial in Sweden, sponsored by NIAID and just begun, which is designed to evaluate several Japanese-developed acellular vaccines.

Work has steadily progressed on the development of a new and improved acellular pertussis vaccine with the intramural program at NICHD. The candidate vaccine has great potential for being non-toxic and protective against disease in infants. Scientists at NICHD are about to start clinical trials pending FDA approval.

Question. If the existing vaccine goes off the market, do we have a back-up plan?

Answer. It is essential that we do everything possible to encourage continued use of the presently licensed pertussis vaccine until new and improved vaccines are put into use. In countries that have stopped vaccination, such as Sweden and Great Britain, a significant increase was observed in the number of reported cas s of pertussis.

A number of actions have been taken by the Public Health Service in recent years to avert disruption of pertussis vaccine supplies. In addition, several steps have been taken to prepare for the possibility that none of these actions succeeded, and the limited number of domestic vaccine manufacturers stopped production. These latter steps include:

- o Formal and informal communications with foreign and domestic manufacturers who do not currently distribute pertussis vaccine in the United States or who distribute only limited amounts (e.g., Merieux, Sclavo, Michigan Department of Public Health, and Massachusetts State Health Laboratories), to enter the U.S. marketplace.

- o Creation of a vaccine stockpile to improve supply.

- o Discussion of options for an expanded Government role in the procurement or manufacture of vaccines.

- o Collaboration of the PHS Immunization Practices Advisory Committee and the Committee on Infectious Diseases of the American Academy of Pediatrics for the purpose of modifying vaccine recommendations when necessary to obtain maximum benefit from limited supplies of vaccine.

CONSTRUCTION

Question. What is your estimate of the capital needs for the present and future of our biomedical needs?

Answer. Verifiable evidence of the nature and extent of the national need is simply not available. We do know, however, that in 1984 the Federal Government was directly financing only 7 to 8 percent of academic research facilities construction and renovation activity, whereas in 1975 the Federal share was 25 percent. However, through the indirect cost mechanism Federal payments for buildings' use and depreciation represent a source of funds for university capital investment. Correspondingly, capital investments in academic research facilities dropped 44 percent between 1975 and 1982. During the past decade alternative sources of funding have not been able to fill the gap left by the decrease in Federal support, and there is little reason to expect that these circumstances will change in the near future.

Limited available evidence indicates that State and local governments have provided nearly half the funds that were used by academic institutions for research facilities in the period 1980-85. Separately budgeted research funds provided another 30 percent. Presumably the latter includes some indirect cost recovery.

The proportion of dollars awarded for indirect costs associated with competing research project grants has increased 63.6 percent in the last 5 years. Indirect costs now account for 32.5 percent of the average total cost of a research grant award, and resistance to further increases is great. Included in indirect costs are the costs of interest on debts, and depreciation and use allowances.

Question. Three years ago, NIH was asked to do a report on the needs of construction for NIH funded programs. Whatever happened to that report?

Answer. In 1984, Senate Report No. 98-544 recognized the "serious need for a current study of facilities needs"; it then

directs NIH "... to submit a proposal for the participation of NIH in a long-term plan designed to modernize and rehabilitate the national biomedical research physical plant and scientific apparatus..."

In February 1985, NIH reported to the Senate on its participation in an envisioned interagency effort to conduct a study of the Nation's research facilities. After the OMB first concurred in and then withdrew its approval for conduct of the interagency study in October 1984, NIH began to develop an independent approach to assessing biomedical research facilities needs. Since that time, the NIH has developed and tested survey forms designed to secure the kinds of information that would be needed to formulate responsibly the requested long-term plans. A plan for a full-scale survey has been developed in preparation for review within the Executive Branch under the terms of the Paperwork Reduction Act.

Late last year, the NIH elected to reassess its plans because of the National Science Foundation (NSF) authorization legislation passed in November 1985, which directs that agency to conduct the necessary surveys and to report to the Congress every 2 years on the research facilities needs of universities. The NIH has initiated discussions with the NSF to determine how the facilities needs specific to biomedical research might best be assessed within the transscience scope of the charge to NSF. The first NSF report is due September 1, 1986.

Question. Why haven't you implemented the recommendations?

Answer. There were no recommendations that called for specific implementation through the budget process. The principal issues continue to be: What are the facilities requirements of the institutions that perform biomedical research, especially institutions of higher education? How can these needs best be estimated without time-consuming, burdensome, and overly costly surveys? To what extent is it either necessary or desirable for research agencies of the Federal Government to participate directly in funding research facilities?

Question. Are you aware of the Keyworth report on capital needs? And the American Cancer Society report?

Answer. The NIH is not aware of a "Keyworth report on capital needs" but is familiar with the testimony given on July 30, 1985, by Dr. Bernadine Healy, former Deputy Director of OSTP, before the House Subcommittee on Science and Technology.

NIH staff have studied the American Cancer Society report and note that 77 percent of cancer research facilities are in satisfactory condition.

GRANTS

Question. We have placed a great deal of emphasis on the number of grants in the past few years. During that time, what has happened to the other programs like: intramural research, training, clinical trials, equipment, and construction programs? Are we funding grants

at the expense of these programs? Should a more balanced approach be taken?

Answer. The following table shows the effect by mechanism of the growth of the NIH budget from FY 1983 to the FY 1986 revised estimate, including AIDS:

(Dollars in Millions)

Mechanism	FY 1983	FY 1986	Percentage Change
Research Project Grants...	$2,095	$2,868	37%
Research Centers.....	373	467	25
Other Research Grants.....	218	298	37
Research Training.....	165	209	27
R&D Contracts.....	320	357	12
Intramural Research.....	498	559	12
Research Management and Support.....	201	206	2
Disease Control.....	53	61	15
Construction.....	3	8	167
National Library of Medicine.....	46	55	20
Office of the Director....	26	89	242
(Small Minority College Program).....	(-)	(10)	(N/A)
(AIDS).....	(-)	(53)	(N/A)
Buildings and Facilities..	15	14	-7
TOTAL.....	4,013	5,192	29
(Clinical Trials).....	(214)	(274)	28

While the support of investigator-initiated research has been our highest priority and has grown faster than the other mechanisms, we have also made every effort to maintain a balanced program of research activities. Even in these years of fiscal austerity, the NIH will continue to make every effort to maintain a balanced program of biomedical research.

FTEs

Question. How many people are employed by NIH now compared to four years ago?

Answer. The current on-board strength as of February 1986 was 13,062 full-time-permanent and other-than-full-time permanent employees who count against the FTE ceilings, compared to 12,969 in February 1982.

Question. What impact have these cuts in personnel and a hiring freeze had?

Answer. The NIH FTE level for FY 1986 is 12,649, a decrease of 451 from the FY 1985 level of 13,100 FTEs and 1,012 from the FY 1984 level of 13,661 FTEs. The reduction in personnel has necessitated a re-evaluation and reprioritizing of program resources, selective

hiring restrictions, continuing review of selected functions/services for possible contracting-out, and the elimination of the summer program.

AIDS FUNDING

Question. How much did NIH request, by Institute, for AIDS work for FY 1987--its original request?

Answer. The following amounts were included in the original FY 1987 request to the Public Health Service in September 1985:

NCI.....	$52,392,000
NHLBI.....	11,611,000
NIDR.....	2,081,000
NINCDS.....	1,575,000
NIAID.....	74,305,000
NEI.....	104,000
DRR.....	1,800,000
TOTAL.....	143,868,000

Question. How much did OMB include in the FY 1987 budget request, by Institute, for AIDS research at NIH?

Answer. In the FY 1987 President's Budget, all AIDS funding is contained within the request for the Office of the Assistant Secretary for Health for subsequent reimbursement to the PHS agencies. The anticipated reimbursement to the NIH, by Institute, is as follows:

NCI.....	$47,151,000
NHLBI.....	17,091,000
NIDR.....	2,733,000
NINCDS.....	1,575,000
NIAID.....	67,520,000
NICHD.....	674,000
NEI.....	104,000
DRR.....	6,142.000
TOTAL.....	142,990,000

Question. Please provide, by Institute, NIH's AIDS allocation under the FY 1986 appropriation passed by Congress last year.

Answer. The table on the following page displays the estimated AIDS funding, by Institute, in FY 1986.

NATIONAL INSTITUTES OF HEALTH

AIDS FUNDING SUMMARY, 1986 HISTORY
(Dollars in thousands)

	Approp.	Sequestration	Rescission	Amounts Available	Planned Allocation	Current Estimate
NCI.....	$28,441	-$1,223		$27,218	+$13,450	$40,668
NHLBI.....	11,200	-482		10,718		10,718
NIDR.....	684	-29		655	+1,057	1,712
NINCDS.....	1,500	-65		1,435		1,435
NIAID.....	27,067	-1,164		25,903	+35,527	61,430
NEI.....	100	-4		96		96
DRR.....	1,731	-74		1,657		1,657
OD.....	70,000	-3,010	-13,915	53,075	-50,034	3,041
TOTAL, NIH...	140,723	-6,051	-13,915	120,757		120,757

Questions Submitted by Senator Arlen Specter

ANIMAL WELFARE CENTERS

Question. I wrote to you, Dr. Wyngaarden, on January 30, 1986, concerning the NIH review of the Animal Welfare Assurance submitted by the University of Pennsylvania on December 23, 1985. What is the status of the NIH review of the University of Pennsylvania's Animal Welfare Assurance?

Answer. Based on an intensive evaluation of the University of Pennsylvania's laboratory animal care use program, the NIH has removed the temporary restraints on new commitments of funds for laboratory animal research to the University of Pennsylvania. This action does not rescind any restrictions previously placed on research involving nonhuman primates at the University's Experimental Head Injury Laboratory.

The NIH has provisionally accepted the University's animal welfare assurance document, which describes an acceptable program for laboratory animal care and use at the University. Although not yet fully implemented, the program meets the provisions of the Public Health Service animal welfare policy and the NIH Guide for the Care and Use of Laboratory Animals.

RESEARCH CENTERS

Question. The NIH request for research centers in 1987 is $447 million, which will support 523 centers. The proposed funding level reflects an $18 million cut. What will be the impact of this reduction on the work of research centers?

Answer. The FY 1987 reduction for research centers will be achieved through reducing the number of centers by 11, from 534 centers in FY 1986 to 523 in FY 1987. No ongoing centers will be terminated; however, funding for selected new centers will be delayed, and some centers that will become eligible for renewal will not be continued. In addition, the average costs of research centers will be reduced, causing decreases in the size and scope of certain projects.

It is difficult, at this time, to ascertain the exact impact of these reductions. It is likely, though, that the proposed decreases in the numbers as well as reductions in the size and scope of centers will somewhat slow the translation of research discoveries to the bedside. However, in the context of limited resources and the overall FY 1987 request for NIH, I believe that the level of funding provided for research centers is appropriate and that it is sufficient to maintain a strong and productive research centers program.

SMALL AND MINORITY UNIVERSITIES AND COLLEGES PROGRAM

Question. Funding in FY 1986 for biomedical research development in small and minority schools would be cut $9 million. Why have you cut funds for institutions which are just beginning to develop biomedical research capability?

Answer. The NIH is proposing to rescind in FY 1986 approximately $9.1 million from the small and minority universities and

colleges program in addition to a reduction of $0.9 million resulting from the Balanced Budget and Emergency Deficit Control Act. The Congress provided $20.0 million for this program in the FY 1986 appropriation, an increase of $10.0 million over both the FY 1985 funding level and the FY 1986 request. Given the need to reduce Federal expenditures because of the growing deficit, the Administration believes that such a significant add-on is unnecessary for a new program begun in FY 1985 with an initial appropriation of $10.0 million.

The NIH is fully committed to solving minority health problems. The FY 1986 revised estimate of $10.0 million provides solid support for this program.

Questions Submitted by Senator William Proxmire

INDIRECT COSTS

Question: Dr. Wyngaarden, last year in a response for the record, you indicated that a uniform, government-wide, indirect cost policy would be desirable and gave us an example of current inconsistencies, such as the fact that the National Science Foundation sets an indirect cost rate applicable over the life of a grant while the NIH rate is adjusted to allow additional amounts of indirect cost to be recovered. Has NIH considered the possibility of conforming to the NSF model?

Answer. The Department of Health and Human Services is considering a major change in the policy regarding the reimbursement of indirect costs. If adopted, the change would generally deny an upward adjustment for indirect costs resulting from the negotiation of a rate above that used in the award process. The process contemplated is a variant of that employed by the National Science Foundation; the primary difference would be that the grantee organization would not be allowed to charge the grant for indirect costs in excess of the awarded amount, nor would it be able to reduce the direct cost portion arbitrarily to increase its indirect cost reimbursement.

Question. How much would NIH save if it adopted the NSF approach of setting a single indirect cost rate for the life of the grant?

Answer. We estimate an annual saving of approximately $5 million in current year budget authority under the NSF approach. We would have similar savings under several variants of the NSF approach that NIH staff have examined and view as better suited to fulfilling the NIH mission and maintaining an effective partnership with awardee institutions, especially research intensive institutions of higher education.

PERCENTAGE OF APPROVED APPLICATIONS RECEIVING FUNDING

Question. Dr. Wyngaarden, in order to form some idea of how your proposal to reduce the number of new investigator-initiated research grants would affect the system, I'd like to know what percentage of approved applications would be likely to receive funding in FY 1987 as compared to the percentage funded in FY 1986, 1985, and 1984. I realize that it may be difficult to make this projec-

tion, but I'd like to get a rough idea of the general trend in this area.

Answer. Approximately 27.4 percent of approved competing applications will be funded in FY 1987 as compared to 30.7 percent in FY 1986 and 37.3 percent in FY 1985 and 1984.

INDIRECT COSTS

Question. An issue that will receive a substantial amount of attention over the next few months is indirect costs. As you know, the Administration is proposing a 26-percent-of-direct-costs cap on the administrative component of indirect research costs effective April 1, 1986, with a cut to 20 percent effective April 1, 1987.

I have been particularly concerned over the failure of indirect costs to be considered as a part of each NIH research proposal. They are computed after the fact and, until I inserted language in a Committee report a few years ago mandating their disclosure, were not even included in individual grant award announcements.

A panel of 13 industry and academic leaders recently came out with a report on indirect costs which, among other things, recommended that all Federal agencies adopt the National Science Foundation practice of including indirect costs in the project budget subject to review.

Do you agree with this recommendation and, if so, when will it be implemented by NIH?

Answer. The NIH is currently reformulating the standard PHS grant application form so that, among other things, it will display the full costs being requested. Under the terms of the Paperwork Reduction Act, this proposed change to the application form will require OMB approval before it can be implemented.

Through this approach of displaying full costs, peer reviewers would have the opportunity to know the requested reimbursement for indirect costs and to comment on any apparent anomalies. However, peer review groups will not be empowered to effect changes directly or arbitrarily in the amounts requested for reimbursement of indirect costs. As always, final decisions affecting indirect costs will be made by those having the relevant expertise. Specifically, officials in the regional offices of the Department of Health and Human Services will establish indirect cost rates, and staff of the National Institutes of Health will check each application to ensure that the rate is cited and applied correctly.

NIH REVIEWS

Question. Dr. Wyngaarden, Secretary Bowen's prepared statement, as submitted to the Committee yesterday, contained the following comment: "NIH will devote greater cost consciousness in the review and funding of project proposals." Does this mean that NIH will require grantees to absorb more of the costs of doing individual research projects, or be inclined <u>not</u> to fund projects that seem too expensive, or both?

Answer. All project proposals are currently reviewed carefully

for scientific merit and for appropriateness of budget. Our peer review groups are knowledgable about the cost of research and the facilities available at the institutions submitting the requests. Furthermore, these groups spend considerable time reviewing the requests. The intention of the quoted statement is that we will increase our efforts in this area. Staff will have greater input, as will the peer review groups and Councils, to assure budgets are appropriate. The awarding BID staff will also review applications carefully before awards are made so that costs can be reduced wherever possible. We do not intend to have grantee institutions absorb an inappropriate share of the expenses of doing research, nor do we intend to rule out important research because it is expensive. Our intent is to assure that the funds allocated are even more carefully scrutinized than is now the case.

NIH ANIMAL CARE GUIDELINES

Question. I understand NIH has revised its guidelines concerning the care and treatment of animals. Do the guidelines address the use of animals in educational demonstrations and practice surgery laboratories?

Answer. The Public Health Service Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions is applicable to any PHS-funded activity in which live vertebrate animals are used or intended for use in research, research training, experimentation or biological testing, or for related purposes. Thus, the guidelines do address the use of animals in educational demonstrations and practice surgery laboratories when they are part of PHS research programs.

Question. As you probably know, a similar document concerning animal care issued by the Canadian Council of Animal Care prohibits the "use of painful experiments solely for student instruction or for demonstrating already established scientific knowledge." That sounds reasonable to me. Was any consideration given to adopting the same policy?

Answer. The Canadian policy was well known to the PHS staff who developed the U.S. policy. It is very similar to that in P.L. 99-158 recently passed by Congress. The PHS policy endorses and is guided by the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training.

Principle IV states the following:

> "Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals."

Principle V states the following:

> "Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or

other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents."

Principle IX states the following:

"Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an institutional animal research committee. Such exceptions should not be made solely for the purposes of teaching or demonstration."

These few quotations from the Principles provide evidence of the similarity between the Canadian and U.S. policies to preclude the unfortunate situations you have mentioned.

REPORT OF OFFICE OF TECHNOLOGY ASSESSMENT
ON USE OF ANIMALS IN RESEARCH AND TESING

Question. NIH and, in particular, the National Cancer Institute would be the agencies most likely to produce alternatives to the use of animals in toxicological testing, according to a report issued last month by the Office of Technology Assessment. OTA suggested that research and development on alternatives to animal testing could be directed specifically to small intramural and extramural pilot research programs in order to assess whether or not targeted development is effective. Will this be included in NIH's report to Congress regarding alternatives as mandated under the Health Research Extension Act of 1985?

Answer. An analysis and discussion of the suggestion made in the OTA report will be included in the NIH report to Congress as mandated in P.L. 99-158, Section 4. If the suggestions prove meritorious and practical, a plan for their implementation will also be provided.

Question. OTA further recommended that NIH establish postdoctoral training programs similar to its " . . . National Research Service Awards, to ensure a steady supply of young researchers schooled in traditional disciplines, ranging from molecular biology to animal behavior, with applications in the development of alternatives." Will this area of training be covered in the mandated report?

Answer. The recommendations will be examined and analyzed for merit. Any actions warranted regarding establishment of postdoctoral training programs similar to current National Research Service Awards would appear in the NIH report. It is possible that some current training programs in place throughout NIH's extramural programs already meet the training needs expressed in the OTA report.

PHS POLICY ON HUMANE CARE AND USE OF LABORATORY
ANIMALS BY AWARDEE INSTITUTIONS

Question. The revised PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions indicates that an average daily census of all species used in each facility is now collected. Can you tell us why?

Answer. The daily census is called for as a means of determining an accurate measure of the numbers and species of animals that institutions use in research. The census also allows for an assessment by the PHS as to whether an institution's laboratory animal care and use program is structured in such a way as to meet the needs of the animals and the research in which they are involved.

Question. Does this duplicate any reporting requirements mandated under the Animal Welfare Act?

Answer. The PHS animal welfare assurance policy requests a daily inventory of all vertebrate animals to provide some idea of the size and scope of the research programs at the awardee institutions. The USDA requires a report on the "animals used in actual research and experimentation." Exempt from the reporting requirements are birds, aquatic animals, rats and mice, and domestic farm animals. The two reports are not the same and do not duplicate each other.

Question. If not, will this information be shared with the Department of Agriculture which, as you know, administers the Act?

Answer. This information will indeed be shared with the Department of Agriculture. The NIH has signed a Memorandum of Understanding with the USDA to share this kind of information.

CONSULTING SERVICES

Question. Dr. Wyngaarden, I note that obligations for NIH consulting services are scheduled to jump from $19,831,000 in FY 1985 to $26,409,000 in FY 1987, an increase of about one-third. Can you tell the Subcommittee why these costs are going up so sharply at a time of budget austerity?

Answer. The NIH anticipates the need for increased use of consultant services in FY 1987 because of several important factors: increases in legislatively mandated Program Evaluation activities; the establishment of the new National Institute of Arthritis and Musculoskeletal and Skin Diseases; newly mandated clearinghouse and advisory board activities (e.g., a Kidney Board and clearinghouse); and cyclical funding of other clearinghouse activities.

RESEARCH CENTERS

Question. Dr. Wyngaarden, you will have to close about 11 research centers in FY 1987 if we approve your budget request. Can you tell us how those research centers will be chosen?

Answer. The FY 1987 reduction of 11 centers would be achieved by delaying funding for proposed new centers and by discontinuing some centers that would be eligible for renewal. The decisions as to precisely which centers would be unfunded will be based on the scientific merit of the applications received and the research priorities of the individual Institutes.

Questions Submitted by Senator Daniel K. Inouye

NATIONAL CENTER FOR NURSING RESEARCH

Question. The FY 1987 budget proposed by President Reagan would eliminate funding for the newly enacted National Center for Nursing Research. Congress made its support of the new Center very clear in its override vote last Fall. In light of that vote, what are your plans for establishing the National Center for Nursing Research in the context of the President's budget request?

Answer. The NIH has taken what action it can to implement the Section of P.L. 99-158 that establishes the National Center for Nursing Research (NCNR) at the National Institutes of Health. This has included a review of the staff, budget, and space allocated to the Center for Nursing Research operation at HRSA/DN and preparation of a legislative implementation plan.

Question. What is your timetable for establishing the new National Center for Nursing Research? Specifically, when do you expect to have an NCNR Director on board? When do you expect the FTE transfer from HRSA to NIH to take place? When will the first NCNR grants review cycle at NIH take place?

Answer. The timetable for establishing the new Center is dependent upon the resolution of the President's rescission package pending before Congress. The NIH would expect to initiate a Search and Screen Committee to identify an NCNR Director as soon as the request to establish the position is approved. Given the required process of search and screen activities, it is unlikely that a Director could be appointed before September 1986 and more probable that a Director would not be in place until January 1987.

The FTE transfer from HRSA to NIH would take place as soon as possible after the FY 1986 budget for the NCNR is resolved.

The first NCNR grants review cycle under the auspices of the NIH will be conducted as soon as the Center is established, probably commencing with the June review.

NATIONAL CANCER INSTITUTE

STATEMENT OF VINCENT T. DeVITA, JR., M.D., DIRECTOR

ACCOMPANIED BY:

JAMES B. WYNGAARDEN, M.D., DIRECTOR, NATIONAL INSTITUTES OF HEALTH

JOHN P. HARTINGER, FINANCIAL MANAGER, NATIONAL CANCER INSTITUTE

DR. ANTHONY S. FAUCI, DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

INTRODUCTION OF ASSOCIATE

Senator WEICKER. The next institute that we will hear from is the Cancer Institute, and we will hear from Dr. Vincent DeVita, the Director.

Dr. DeVita, please introduce your colleagues who accompany you to the table. Again, a very warm welcome, and my respect for the work that you are doing.

Dr. DEVITA. Thank you, Mr. Chairman.

With me is John P. Hartinger, who is the Financial Manager of the Cancer Institute.

PREPARED STATEMENT

Mr. Chairman, I would like to submit my full statement for the record and just make a few comments in reference to progress in the Cancer Institute over the last year since we met.

[The statement follows:]

STATEMENT OF VINCENT T. DEVITA, JR.

A basic tenet of the cancer program is that the understanding of how a normal cell becomes malignant is a requirement for the ultimate successful prevention and treatment of cancer. A corollary to this tenet is less widely appreciated: it is possible to prevent and to treat diseases including cancer even before full knowledge is available. Now, based on new knowledge of cancer biology, major efforts are under way to prevent cancer; to reverse the cancer process by nudging a transformed cell back to normal; to employ the exquisite network of our immune system to defend against cancer; to refine treatment and destroy more selectively cancer cells; and to block metastasis--the ability of cancer cells to spread and kill. The investment in basic research made possible by the National Cancer Program has led us today to an unprecedented understanding of the cancer cell.

This year, another piece of the cancer puzzle fell into place. Humans, like other living organisms, live in a sea of environmental toxins, most produced naturally, that are used to preserve each living organism's ecological niche. A simple example of this is the production of antibiotics by organisms in the soil to control the population of competing bacteria. We as physicians exploit these chemicals to treat bacterial infections and some cancers. A new conceptual unity has emerged that now connects such distant events as drug resistance in advanced cancers with the same fundamental mechanism of cancer transformation itself. It is now apparent that a common set of genes controls enzyme systems that resist the carcinogenic effects of environmental toxins and help prevent cancer in animals and humans. The ultimate failure of this process is followed by the loss of control of the switches that regulate growth, leading to malignancy. However, we now know that cancer cells retain these defenses in some capacity and are able to resist the very chemicals used to treat them. We can use this information on a practical level since modification of these resistance genes could improve treatment with drugs with potentially startling simplicity.

Cancer cells are renegades. They exert lethal effects by growing out of control, but they appear to be immature, somewhat confused cells, aberrantly using the same genetic mechanisms established for normal growth and development. The new biology allowed researchers to tap into this genetic machinery at the heart of the cell and find minute, but critical, differences in genes of normal and cancer cells. They discovered oncogenes involved in transforming healthy cells to cancer. The counterparts of these genes, proto-oncogenes, are involved in normal growth and development. It has long been thought that cancer is a multistage process with intricate circuits and switches, working at different points of disease progression and at different times. Some substances serve as initiators that start but cannot finish the cancer-causing process without the help of promoters. Most promoters cannot work in cells that have not been initiated. With new technology, we can study the genetic switches which trip the cascade of events that control growth and development or lead to cancer. Although cancer is over 100 different diseases, we now feel certain they share some basic mechanisms that set off the disease and have already exploited some of these data at the clinical level.

Recent research in cancer etiology has focused on how promoters

work, because interfering with promotion may yield results by preventing cancer in persons exposed to initiators and offers the best hope in our lifetime of reducing cancer incidence. Powerful evidence already exists that this approach works. For example, curtailing wide use in the 1970's of the "promoter" estrogen, used for menopausal symptoms, led to a dramatic, fast reduction in uterine cancer. Cigarette smoke contains both initiators and promoters, but the removal of the promoters' effect may be the key event in avoiding lung cancer. This year, NCI reported that the incidence of lung cancer in white men has decreased significantly for the first time in at least 50 years. This provides evidence that the exposure to chemical initiators in cigarette smoke does not irreversibly destine a person to develop cancer and that people can reduce their cancer risk by interrupting the carcinogenic process at its later stages by quitting smoking. This type of evidence is the basis for multiple prospective intervention trials in progress at NCI to test the hypothesis that cancer can be prevented. The time interval to reduce risk may not be long in human terms. For example, the interval from smoking cessation to a return to normal risk of cancer is about a decade for most smoking-related cancers in man.

To emphasize these points further, I would like briefly to highlight a few past accomplishments and some current plans in cancer biology, prevention, diagnosis, and treatment.

Basic Biology

The development of major new technology has allowed scientists to put knowledge to work. Some brilliant Nobel-prize-winning discoveries of the 1970's led to development of many techniques that are routinely used today by scientists to cut, splice and analyze genes in detail (known as recombinant DNA technology). With these tools, researchers are able to probe, isolate, sequence, and scrutinize pieces of DNA, decode nature's messages, and make constructs of genes artificially. A technique called "marching down the chromosome" is streamlining studies of the DNA sequences that flank oncogenes and contain control switches. Using synthetic DNA probes that stick to oncogenes, scientists isolate and use the ends of large DNA fragments to probe and isolate additional ends of DNA further along the chromosome. This way, control elements can quickly be identified, compared, and sequenced.

An oncogene may be activated by mutation caused by a chemical, a virus, radiation, or as a result of a chromosomal break that moves the oncogene to a new location. Here it might be placed next to a signal switch that is normally "on" to produce normal protein, but, in this case, keeps the oncogene "abnormally on." Evidence of the activated *ras* oncogene (which has a mutation) has been found in a number of common human cancers, including lung, colon, and bladder cancers, and the *myc* gene in a lymphoma. Five different oncogenes associated with leukemias and lymphomas have been identified with specific translocation of pieces of chromosomes.

A few years ago, our researchers focused on the discovery of oncogenes, then their control switches, and now this work has moved toward understanding the products made by oncogenes and molecularly characterizing tumors as the new pathology. This year, protein products of the *erb*-B and *fms* oncogenes were found to be defective receptors for growth factors (substances that stimulate cell growth).

The study of oncogenes and their control is also moving from the laboratory dish to studies in live animals. It is now possible to make combinations of different oncogenes and flanking DNA sequences in the laboratory, then inject these "foreign" genes into fertilized mouse eggs and produce mice (transgenic mice) in which every cell contains the foreign genes. The use of transgenic mice is an invaluable tool to examine ways to interrupt oncogene function and prevent or reverse the malignant process.

At the clinical level, oncogenes influence the aggressiveness of cancer cells and their ability to spread and invade distant, vital organs, causing death. Activation of more than one oncogene, and the presence of many copies of a single oncogene (gene amplification) have been closely linked with this metastatic process in lung, colon, and breast cancer.

Last year, NCI made major contributions in many areas of AIDS research. These included advances in understanding the molecular biology of the AIDS virus, HTLV-III; understanding the natural history and transmission of AIDS; identifying potential new therapies for the disease; and developing a vaccine and an animal model for the disease.

Cancer Prevention and Control at the Practical Level

The multistep process of carcinogenesis led the NCI to investigate practical ways to prevent cancer by interfering at the clinical level with the late, "promotion" stages of the process, some of which may be under control of known oncogenes. Evidence suggests that dietary fat serves as a promoter of cancer, while fiber protects colon cells from the effects of carcinogens. A study called the Women's Health Study is under way to determine whether low-fat diets can reduce breast cancer incidence in women at high risk for the disease. Studies are also looking at how fiber works to reduce risk of cancer. Recent studies point to the inhibitory role of both phytic acid (present in grain fibers) and uronic acid (in vegetable fiber).

Already 450 agents, some of them micronutrients, have been identified as possible inhibitors of cancer; in-depth analysis has begun on 15 percent of them. Twenty-six human chemoprevention studies (adding selected micronutrients such as vitamins A, C, E, and beta-carotene to diet) continue in an effort to interfere with the promotion stages of the cancer-causing process. The NCI is funding 34 intervention studies--involving about 5 million people--to find ways to reduce smoking. Adolescents, minorities, and women are targeted.

Meantime, NCI's SEER (Surveillance, Epidemiology, and End Results) Program tracks the incidence, survival, and mortality rates of cancer in the United States. These data, recently reviewed in depth at a National Cancer Advisory Board seminar, clearly show that progress made in cancer treatment has had a significant impact on national cancer survival statistics. Today, 50 percent of patients with serious cancers are curable, but 50 percent are not. The NCI has launched a special initiative to address the problem of excess cancers and cancer deaths (avoidable mortality) among minority populations.

Cancer Diagnosis

Monoclonal antibodies, designed to "home in" on cancer cells, already are being used to diagnose tumors, such as lymphomas, leukemias, and colon cancer. Monoclonals help detect metastatic breast cancer cells in the body fluids of some patients, and may be useful in finding hidden metastases in some patients with colon cancer and melanoma.

On another front in diagnosis, scientists are improving the use of Magnetic Resonance Imaging (MRI) to attempt to distinguish cancer from benign tumors. MRI is proving useful for defining tumors in lung, liver, brain, and other organs.

Cancer Treatment

A major, achievable goal in cancer treatment will be to characterize oncogene products and develop new strategies to inhibit their production or action. There is already a startling and practical clinical example where selection of therapy based on patterns of oncogene expression has led to improved results. Such approaches are being explored in a variety of tumors.

Progress continues in refining surgery, radiotherapy, and chemotherapy as effective treatments for many cancer patients, and biological agents are rapidly adding to the therapeutic armamentarium. The NCI's Biological Response Modifier Program, established in 1980, is playing a substantial role in bringing new agents to clinical trial. Using recombinant DNA technology, the genes of several body proteins, interferon, Interleukin-2 (IL-2), and tumor necrosis factor, have been prepared in large enough quantities to initiate clinical studies. This year, a very promising trial of biologicals was reported, using adoptive immunotherapy--the transfer of anticancer immune cells directly to the cancer patient. Early results in patients with advanced cancers who were treated by these IL-2 Activated Killer (LAK) cells and very high doses of IL-2 have been most encouraging, especially in cancers of the kidney, the colon, and melanoma. The NCI is now testing this treatment across the country in its network of cancer centers and cooperative clinical groups.

Chemotherapy is improving as well. During 1985, adjuvant chemotherapy used after surgery produced positive results in heretofore difficult-to-treat cancers such as breast, rectal, colon cancer, and adenocarcinoma of the lung. The resistance that certain cancer cells develop to drugs, alluded to early in this statement, has been a major obstacle to curing some common cancers with drugs. A surface marker associated with this drug resistance has been identified and an antibody to the marker reverses drug resistance in the laboratory. This will be tested in the clinic in the next year.

Recently, understanding the deadly process of metastasis has led to a new approach to block it. Cancer cells spread by adhering to a protein laminin, found on the lining of blood vessels. Small fragments of laminin have been prepared which can block the cancer cells' laminin receptor and so prevent attachment to laminin on the vessel's basement membrane. This novel treatment approach begins clinical trials this year.

Human cells from small cell lung cancers produce a growth factor known as bombesin, capable of stimulating the cancer's own growth. A monoclonal antibody against bombesin is now entering clinical trial.

Mr. Chairman, the Fiscal Year 1987 budget request for this Institute is $1,158,089,000. I will be happy to answer any questions.

Biography of Vincent T. DeVita, Jr.

DATE AND PLACE OF BIRTH:	March 7, 1935, Bronx, New York
EDUCATION:	1957 - B.S. (Chemistry), College of William and Mary, Williamsburg, Virginia
	1961 - M.D. (with distinction), The George Washington University School of Medicine, Washington, D.C.
POSITIONS HELD:	
1961 - 1962	Internship, University of Michigan Medical Center, Ann Arbor, Michigan
1962 - 1963	Residency in Medicine, The George Washington University Medical Service, District of Columbia General Hospital, Washington, D.C.
1963 - 1965	Clinical Associate, Laboratory of Chemical Pharmacology, National Cancer Institute, National Institutes of Health, Bethesda, Maryland
1965 - 1966	Senior Residency in Medicine, Yale-New Haven Medical Center, New Haven, Connecticut
1966 - 1968	Senior Investigator, Solid Tumor Service, Medicine Branch, National Cancer Institute, Bethesda, Maryland
1968 - 1971	Head, Solid Tumor Service, Medicine Branch, National Cancer Institute, National Institutes of Health, Bethesda, Maryland
1971 - 1974	Chief, Medicine Branch, National Cancer Institute, National Institutes of Health, Bethesda, Maryland
1974 - 1980	Director, Division of Cancer Treatment, National Cancer Institute, National Institute of Health, Bethesda, Maryland
1975 --	Clinical Director, National Cancer Institute, National Institutes of Health, Bethesda, Maryland

1980 --	Appointed by the President as Director, National Cancer Institute, National Cancer Program, National Institutes of Health, Bethesda, Maryland

ACADEMIC APPOINTMENTS:

1971 - 1975	Associate Professor of Medicine, The George Washington University School of Medicine, Washington, D.C.
1975 --	Professor of Medicine, The George Washington University School of Medicine, Washington, D.C.
1985 --	Consulting Medical Staff, Internal Medicine/ Medical Oncology Department, National Naval Medical Center, Bethesda, Maryland

EDITORIAL BOARDS:

1968 - 1974	Associate Editor, Journal of the National Cancer Institute
1970 - 1974	Scientific Editor, Cancer Chemotherapy Reports
1975 --	Advisory Editor, International Journal of Radiation Oncology, Biology and Physics
1977 - 1981	Associate Editor, Editorial Advisory Board, Cancer Research
1978 - 1980	Member, Board of Medical/Scientific Consultants, Cancer Nursing
1979 - 1984	Member, Editorial Board, Seminars in Oncology
1979 - 1981	Associate Editor, The American Journal of Medicine
1977 --	Member, Board of Scientific Council, Cancer Chemotherapy and Pharmacology
1977 --	Associate Editor, Cancer Clinical Trials
1977 - 1978	Member, Editorial Board, American Federation of Clinical Oncologic Societies
1979 - 1980	Member, Editorial Board, American College of Physicians (A.C.P.), Audio Cassette Program
1980 --	Member, Editorial Board, Your Patient and Cancer
1980 --	Member, Editorial Board, International Journal of Radiation Oncology, Biology and Physics
1980 --	Member, Editorial Advisory Board, Breast Cancer Research and Treatment
1981 --	Member, Editorial Board, Cancer Research
1981 --	Member, Editorial Board, Gynecologic Oncology
1981 --	Member, Editorial Board, Hematological Oncology
1982 --	Member, Editorial Board, Physicians' Drug Alert
1982 --	Member, Editorial Board, Cancer Investigation
1982 --	Member, Editorial Board, Journal of Clinical Oncology
1983 --	Associate Editor, Cancer Investigation
1983 --	Associate Editor, American Journal of Medicine
1983 --	Advisory Editor, Hospital Practice
1984 --	Member, Editorial Board, Cable Health Network
1985 --	Member, Editorial Advisory Committee, Core Journals in Hemato-Oncology

1986 --	Guest Editorial Member (meritorious), Japanese Journal of Cancer Research

COMMITTEES AND OTHER OFFICES :

1968 - 1970	Councilman, Assembly of Scientists of the National Cancer Institute, National Institutes of Health
1970	Clinical Research Committee, National Cancer Institute
1972	Chairman, Program Committee, American Society of Clinical Oncology, Inc.
1973 - 1976	Board of Directors, American Society of Clinical Oncology, Inc.
1974 --	Member, Albert Lasker Medical Research Awards Jury
1975	American College of Surgeons' Commission on Cancer, Committee on Patient Care and Research
1975 - 1976	Advisory Committee on Clinical Investigations II - Chemotherapy and Hematology, American Cancer Society, Inc.
1975	Publications Committee, American Society of Hematology
1976	Member, Expert Advisory Panel, World Health Organization (WHO)
1976 - 1979	Member, Board of Directors, American Association for Cancer Research
1977 - 1978	President, American Society of Clinical Oncology
1976	Chairman, Treatment Committee of the French-American Agreement, Union Against Cancer
1976 --	Member, Jeffrey A. Gottlieb Memorial Award Committee, University of Texas System Cancer Center
1978 - 1979	Chairman, Special Membership Committee, American Association for Cancer Research
1979 - 1982	Member, Panel of Consultants on Clinical Oncology, International
1981 - 1985	Member, Awards Assembly of the General Motors Cancer Research Foundation
1983 --	Member, Armand Hammer Cancer Award Committee
1984 --	Member, Advisory Council, General Motors Cancer Research Foundation

CERTIFICATION SPECIALTY BOARDS:

1961	Diplomate, National Board of Medical Examiners
1968	Diplomate, American Board of Internal Medicine
1972	Diplomate, subspecialty of Hematology, American Board of Internal Medicine
1974	Diplomate, subspecialty of Medical Oncology, American Board of Internal Medicine
1974	Recertified, American Board of Internal Medicine

PROFESSIONAL SOCIETIES:

Fellow, American College Physicians
Member, American Society of Hematology
Member, American Society of Clinical Oncology
Member, American Association for Cancer Research
Member, American Federation for Clinical Research

1972 Elected, American Society for Clinical Investigations

1976 Member, Society of Surgical Oncology (The James Ewing Society)

1985 Elected, Institute of Medicine, National Academy of Sciences

HONORS AND AWARDS:

Phi Beta Kapp
Alpha Omega Alpha Medical Honor Society
Smith-Reed-Russell Medical Honor Society

1959 Research Fellow with Adrian Hogben, Mount Desert Island Biological Laboratory, Bar Harbor, Maine

1970 "Oren del Sol en el Grando de Official" awarded by the Government of Peru

1972 Visiting Professorship of Medicine (July-August), Stanford University School of Medicine

1972 Albert and Mary Lasker Medical Research Award

1973 First Annual Clowes Lecture, Roswell Park Memorial Institute

1975 Department of Health, Education and Welfare Superior Service Award

1976 Esther Langer Award

1976 Alumni Medallion, The College of William and Mary

1976 Jeffrey Gottlieb Award

1978 Bronze Medal, American Society for Therapeutic Radiology

1979 Karnofsky Prize and Lecture

1980 Griffuel Prize, Association for the Department of Research on Cancer, Paris

1982 James Ewing Award, The Society of Surgical Oncology (The James Ewing Society)

1982 Honorary Doctor of Science, The College of William and Mary

1983 Alumni Achievement Award, The George Washington University

1983 Honorary Membership, Society of Gynecologic Oncology

1983 Honorary Membership, Japanese Cancer Society

1983 Honorary Fellow, American College of Radiology

1983 Memorial Sloan-Kettering Cancer Center Award

1983 Distinguished Service Medal, United States Public Health Service

1983 Honorary Doctor of Science, Ohio State University

1984	Honorary Doctor of Science, The George Washington University School of Medicine
1984	Meyer and Anna Prentiss Award
1984	Member, Honorary Board, Montgomery Hospice Society
1984	Second Emmanuel Cancer Foundation Award
1985	Pierluigi Nervi Award, Rome, Italy
1985	Medal of Honor, American Cancer Society
1985	The Barbara Bohen Pfeifer Award, American-Italian Foundation for Cancer Research
1985	Stratton Lecture, American Society of Hematology
1985	Leukemia Research Fund Lecture, London
MARITAL STATUS:	Married, two children
PRESENT ADDRESS:	9925 Julliard Drive Bethesda, Maryland 20034

MOLECULAR CHARACTERIZATION OF CANCER CELLS

Dr. DeVita. The most exciting event that has happened in the last year, Mr. Chairman, is that we are beginning to appreciate what the cancer cell really is at the molecular level.

We have known for a long time that it is a renegade cell, but we always thought of it as a very dominant cell. Now it seems more and more to be a wobbly, confused cell that is using genetic mechanisms in an aberrant way that are normally there for developmental purposes.

We are now beginning to understand these mechanisms to the extent that we can actually intercede to prevent and treat more effectively.

There is a new tumor pathology developing called molecular characterization. Instead of first looking at tumors under the microscope to classify them, we can now analyze tumors at the molecular level, and we can characterize them. This has reached a practical application since we spoke last year.

MAJOR SCIENTIFIC ACHIEVEMENTS OF PAST YEAR

We spoke last year about oncogenes; and we were quite certain that oncogenes were very important in the malignant process. Our researchers are now looking for the products that they produce, and in the process they found that the products of two oncogenes are defective growth factor receptors that can't receive the normal signals to shut off.

The counterparts of these genes, protooncogenes, are involved in normal growth and development. It has long been thought that cancer is a multistage process with intricate circuits and switches, working at different points of disease progression and at different times. Some substances serve as initiators that start but cannot finish the cancer-causing process without the help of promoters. Most promoters cannot work in cells that have not been initiated. With new technology we can study the genetic switches which trip the cascade of events that control growth and development and lead to cancer.

There is another piece of exciting information. We now have our hands on what we think are the drug resistance genes, the genes that are responsible for a cell's ability to inactivate anticancer drugs. This has puzzled us for many years. It turns out to be the same set of genes that cells use to resist environmental toxins and carcinogens.

We believe that we can inhibit the action of these genes and have studies in progress in this area.

Let me conclude by saying that it has been a very exciting year in treatment. Dr. Wyngaarden has already mentioned the interleukin-2, and lymphokine activated killer cell project which has produced very exciting results in kidney, melanoma, and colon cancer.

Chemotherapy is improving as well. During 1985, adjuvant chemotherapy used after surgery produced positive results in common cancers such as breast cancer, rectal and colon cancer, and adenocarcinoma of the lung. We also had two studies of bladder cancer which showed a response like we have never seen before.

Next year, we will be taking the molecular characterization I described into the clinical trial level. We have already shown that by characterizing at the molecular level, we can select a therapy from a different category than would otherwise have been chosen that works well. We will apply this approach to identify previously untreatable tumors that may respond to the appropriate treatment.

The underpinning of all of this is a greater understanding of why cells become malignant. This is a major accomplishment of basic research supported by the Cancer Program since its inception 50 years ago. You may be interested to know that we are celebrating our 50th anniversary at the same time that the National Institutes of Health is celebrating its centennial.

This concludes my comments. Our budget for fiscal year 1987 for this Institute is $1,158,089,000.

I will be happy to answer any questions.

PROGRESS IN AIDS RESEARCH

Senator WEICKER. Who is going to cover the AIDS area, Dr. Fauci, or Dr. DeVita?

Dr. DEVITA. We can do it jointly, or I will be glad to answer questions.

Senator WEICKER. Dr. Fauci, why don't you join us at the table, so that we don't go over the same ground twice.

Dr. FAUCI. Thank you, Mr. Chairman.

Mr. Chairman, over the past year, there have been a number of very important advances made in AIDS research at the very basic level and with regard to practical applications. The etiologic agent which is responsible for AIDS, namely HTLV-III, was identified 2 years ago. That major breakthrough has allowed a number of diverse studies which have led to well coordinated and active efforts in both prevention through vaccine development research and treatment through antiviral therapies. I know that this has been discussed before, but I wish to

emphasize that the National Institutes of Health has been actively involved in the area of antiviral therapy to the extent that drugs should be available in the future for individuals with AIDS.

Over the past year, we—the National Institute of Allergy and Infectious Diseases in coordination with the National Cancer Institute—have developed a strategy that involves either developing drugs, or taking drugs that have already been developed, screening them for antiviral activity, then evaluating them through the NIAID/NCI AIDS drug selection committee. This committee has the responsibility for determining which of those drugs should go on to further clinical testing.

The clinical testing will be conducted through our AIDS treatment evaluation units, which will be established this summer. These units will undertake phase I, phase II, and possibly phase III testing, hopefully culminating in drugs that will be available on the market.

At the present time there are a number of agents that have been tested for their ability to block virus replication, as well as to restore the immune system.

We do not yet have a cure for this disease, but there are a number of promising agents that are in the hopper and are actively being studied.

There is active research going on, both intramurally and extramurally, toward reconstitution of the immune response in AIDS patients, and we have had some limited, but nonetheless encouraging success.

With regard to vaccine development, the same thing holds true. Now that the virus has been isolated, purified and cloned, we can manipulate the various components of the virus and have them ready for preliminary testing. Thus, we are making an extraordinary amount of progress.

There are also a number of other projects that I will not have time to discuss in detail; I will outline some examples. The first is related to the natural history and epidemiology of the disease, which is being studied not only here in the United States, but worldwide, involving multiple types of mechanisms whereby this virus can be transmitted within the already established risk groups, as well as within the heterosexual population. In addition, there are improved new diagnostic methods. Thus, there is an extraordinary amount of activity, and significant progress has been made over the past year since we last appeared before the committee.

Senator WEICKER. Do you have anything that you want to add?

Dr. DEVITA. I think that Dr. Fauci has covered it very well.

The publication of the drug that is of greatest interest should be within weeks in the journal Lancet. It actually does show positive clinical effects in patients with AIDS. So we are encouraged that we are on the right track, and if you can inhibit the virus, you can actually get immune reconstitution.

I think one of the questions that you had last year was whether or not, once you had AIDS and the immune system was damaged, it was irreversibly damaged.

It looks like if you inhibit the virus, that the immune system has the capacity to come back. This may not be the final drug, or the best

drug, but it is a very important observation for patients with AIDS, they are not irreversibly injured.

Senator WEICKER. Lancet, is that a British publication?

Dr. DEVITA. Yes.

Senator WEICKER. Is that a British study?

Dr. DEVITA. It is a study that was conducted in the intramural program in our institutes, with the collaboration of the people at Duke University on about 26 patients with AIDS, treated with this compound, that was put through our screening and was developed by this committee. We will be going to the larger scale clinical trial shortly.

AIDS—DRUG TESTING

Senator WEICKER. When we discussed this matter last year, it seemed to me at that time that we were discussing four, five, or six drugs that were at a point where you felt they deserved larger clinical trials. Is that still the number?

Dr. FAUCI. The drugs that we mentioned are in various stages of the strategy that I outlined for you. They have proceeded, as expected, through the system during the past year. The ones that were in early development stages have now gone into phase I studies. Those that completed phase I are now going into phase II testing.

In addition, there are additional agents that have been screened by the AIDS drug selection committee over the past several months. We are investigating 29 new drugs to evaluate their use as antiviral agents in AIDS.

This is a very dynamic process. While we are performing clinical testing of one agent, we are in the early stages of development and discovery of new agents.

AIDS—FUNDING

Senator WEICKER. I want to know if there is enough money to allow the process to proceed.

Dr. FAUCI. Assuming that we will receive the reimbursement from OASH, yes, we do. The money that was appropriated by the committee last year is sufficient to go through the procedures that we are discussing right now.

AIDS—NUMBER OF VICTIMS

Senator WEICKER. As we are talking today, what are the figures? What are the latest statistics vis-a-vis those that have been identified as having contracted the disease, and the fatalities?

Can you give me a comparison between 1984 and 1985?

Dr. FAUCI. Yes; right now there have been close to 18,000 cases of what we call full-blown AIDS in the United States. Those are individuals, infected with the virus, who developed the opportunistic infections or the cancers that place them into the empiric category of full-blown disease.

Over the past year, we have seen a doubling of cases. At this time last year there were one-half that number. There were close to 9,000 cases then.

There are also approximately 100,000 to 150,000 people in this country who are infected with the virus and who are not well. They have what we call the AIDS related complex. They do not have the full-blown disease, but they have a variety of symptoms ranging from only malaise or fever to rather severe wasting and debilitation.

The figure that is quite alarming is that in the United States there are approximately 1 million individuals who are infected with the virus, but who are asymptomatic carriers. That is, they have the virus; they are infected, and they are antibody positive. It is possible to isolate the virus from a substantial proportion of them, but they are neither sick nor symptomatic.

Senator WEICKER. What do you think is going to happen to these 100,000 to 150,000 who are symptomatic?

Dr. FAUCI. Right now, based on projections from closely following these individuals over the past 3 years or so, approximately 25 percent to 27 percent of the individuals who have symptoms, that is, who have AIDS related complex, are expected to go on to develop the full-blown disease within 3 years.

Senator WEICKER. What of the million category?

Dr. FAUCI. Although there is some play in the figures, a safe, conservative estimate is that within a period of 3 years, 10 percent of asymptomatic carriers, or 10 percent of those 1 million individuals, will develop the full-blown disease.

There is approximately a 3 percent or so increment per year of individuals converting from seropositive, asymptomatic to full-blown disease. There is a figure that has come out recently of a somewhat higher number, but that is only in one study. If you consider all the studies, I think 10 or so percent would probably be the most accurate estimate.

Senator WEICKER. So right now we are at the 18,000 level, and would it be safe to say that that will double again in this next year?

Dr. FAUCI. Yes, sir.

Dr. DEVITA. The doubling rate now is every 11 months.

Senator WEICKER. The doubling is every 11 months.

Dr. DEVITA. Yes.

AIDS—FATALITY RATE

Senator WEICKER. What is the percentage of fatalities as applied to that 18,000 group?

Dr. FAUCI. The official published fatality rate is 53 percent, but that can be a misleading number because it includes all of the individuals who have been infected with the virus and have the disease. For instance, if a diagnosis was made on an individual only 4 months ago, that person is included in the statistic. The number is, therefore, artificially low. It is very likely that the long-range mortality for the full-blown disease will approach 100 percent because for individuals who

had AIDS diagnosed 4 years ago, it is about 88 or 89 percent. We expect that when talking about 5 to 7 or more years, it will approach 100 percent.

AIDS—EDUCATION

Senator WEICKER. Incidentally, feel free to chip in at any time if there is something that you would like to add.

Is there any reason to believe that through education efforts, contracting of the disease is in the process of being slowed down to any degree?

Dr. FAUCI. Yes; there is, because one of the important and reproducible indicators of sexual activity among risk groups is the incidence of other sexually transmitted diseases, such as gonorrhea and syphilis. Throughout certain centers in this country over the past year there has been a substantial decrease, up to 75 percent, in rectal gonorrhea, which is one of the sexually transmitted diseases most commonly seen in gay men in this country.

What I think we are seeing is an understanding of the risks of multiple sexual partners and having sexual relations with individuals whose prior sexual contacts are unknown to you. That is reflected in the drop in the incidence of sexually transmitted diseases, particularly among the male homosexual high risk group. That will, hopefully, account for, as the years go by, a plateauing effect in the number of transmitted AIDS cases.

We have not really been seeing that plateau yet, but you would not expect to see it for a few years because of the very long incubation period of this disease.

AIDS—PATIENT CARE

Senator WEICKER. I know that this is not directly your concern, but clearly in your travels you get a feel for it. Exactly where do we sit in terms of in-patient care facilities across the country for persons who have AIDS?

Dr. FAUCI. I am not sure what you mean by that question.

Senator WEICKER. In other words, who takes care of them? Every time I pick up the paper, nobody wants to take care of them. Is most of the care done at home?

Dr. FAUCI. Most of the care for the AIDS patients who are sick enough to be in the hospital is administered in the standard general hospitals, both public and private throughout the country.

There are a few centers throughout the country that have established defined categorical AIDS units to take care of AIDS patients. For example, the University of California at San Francisco, and the San Francisco General Hospital have such a unit. They are going to be starting one at Johns Hopkins, and in New York. That is the exception; for the most part, AIDS patients are cared for in the general flow of medical care in hospital centers throughout the country.

Senator WEICKER. But are the hospitals willing to do that in the general flow, or are they refusing to?

Dr. FAUCI. No; they are not refusing. They are taking care of them.

Senator WEICKER. It was at my initiative last year, and I feel that you are pretty good independent judges of this, and I don't want to pursue something that is not necessary. But in the course of preparing the budget last year, if you will recall, I requested $16 million, which would go to facilities to take care of AIDS victims, or at least to start up such a program.

At the time that I made that request, really not very many people were taking on this responsibility, either in general hospitals, or in the community as a whole.

Are you indicating to me that this is really not a problem, that the hospitals are seeming to handle this in the normal course of events.

Dr. FAUCI. At the present time, it depends on whom you ask and what situation you are in, Senator. Right now, I believe that care is adequate, and I think that it has been for some time, and will continue to be.

However, as the number of cases increases, I think that we are going to have a major problem with regard to care. In some medical centers, and I just visited San Francisco a few weeks ago to site visit their unit, one-third of the general medical cases in the hospital are AIDS patients. The same holds true for some hospitals in New York City. If you walk on a medical ward, one-third of the cases are AIDS patients.

Senator WEICKER. Obviously, these possibles are going to be subject to the same ratios and figures that you have discussed as to the overall community of these patients.

AIDS—DRUG DEVELOPMENT

Dr. DEVITA. Part of the drug development effort, however, will offset some of that because when the 10 units go up in the spring, those units will be centers for clinical trials for AIDS. We will be taking more and more cases on clinical trials. We anticipate 2,000 to 3,000 cases a year for trials of just the drugs that we have in hand.

AIDS—DRUG TREATMENT

Senator WEICKER. I realize that guesswork is not your business, but nevertheless as we are sitting here discussing this, I gather you are quite hopeful that something could develop within the next couple of years vis-a-vis the drug treatment as compared to the vaccine; is that right?

Dr. FAUCI. Yes; we are hopeful, but we have to have cautious optimism because this is a very unusual and very tricky virus. If one thinks in terms of a penicillin-like drug, which would completely eliminate the virus from the body, that might be too farfetched. It might not be, but I am somewhat cautious on that.

What we are hoping for are drugs, such as one of the drugs that Dr. DeVita mentioned, which might have the capability of putting the lid on the replication of the virus and holding it in check, but not neces-

sarily completely eliminating it. This drug would be combined with immunologic reconstitution by certain biological factors such as the interleukins or interferons, or perhaps even bone marrow transplantation. If you put these together in what we call our two-pronged approach to the therapy of the virus, then I do have optimism that perhaps within a period of a few years, we might be able to treat a substantial number of those individuals, but that is purely speculative.

Dr. DEVITA. There is one additional point, Senator. Even if we only have partial success in treating persons with AIDS, if the drug renders the patient virus free, they can't shed the virus. That is one way of boxing off an epidemic. If you put people on drugs who are virus positive, they will no longer be virus positive, they won't be a hazard to people around them.

So drug therapy has another dimension in terms of the possibility of controlling the epidemic. I am quite optimistic that we will be able to control the spread of the virus. These kinds of viruses, however, tend to be forever because they integrate into the DNA of the cells. Control of this virus means not allowing it to replicate effectively in the cells, it doesn't mean that you get rid of it. You will probably always find signs of it, but that is probably not an unsurmountable problem.

AIDS—VACCINE

Senator WEICKER. Those are your opinions vis-a-vis chemotherapy. What about the vaccine, where do you think that sits?

Dr. FAUCI. I think work on a vaccine is a good example of how rapidly one can translate basic research on this virus into practical application. A protective mechanism for the body is very likely an immune response against the outer coat or envelope of the virus. Since this virus has been so completely characterized, one can actually take genes from the virus and plug them into another microbe using recombinant DNA technology and have that microbe make large amounts of the viral protein—in this case the envelope.

That purified material is now available, either from recombinant DNA technology or by synthesis since we know the sequences. Early testing of these materials is going on right now in an animal model. We are already at the point, particularly with work that has gone on in the Cancer Institute, where animals have been immunized and they are making an antibody, an antibody which very likely will be able to neutralize the virus.

The next step, which is imminent, is to challenge those animals. If the animals that are challenged can be protected against the virus, then we have made a giant step toward having a vaccine to test in humans.

Dr. DEVITA. Dr. Fauci has covered it very well.

We will be injecting chimpanzees shortly because the chimpanzee can develop a disease when you inject them with the AIDS virus. So we can see if they can resist the disease as a result of the vaccination.

At that point in time, we would have a product. NIAID has the vaccine evaluation units already in place and we would transfer the prod-

uct to them. They would begin to worry about the very complex problem of whom you immunize, and how you immunize. It is not an easy situation, but at least we will have something to work with.

AIDS—HETEROSEXUAL TRANSMISSION

Senator WEICKER. Is there an increase of AIDS among the heterosexual population?

Dr. FAUCI. In the United States, there is an increase in numbers, but there is not an increase in the relative proportion of cases, given the total AIDS picture. One percent of the cases are heterosexually transmitted.

However, there is recent information concerning the presence of this virus in prostitutes and in Armed Forces personnel. A study from the Walter Reed Army Medical Center has shown that there are a number of Armed Forces personnel who got the virus very likely through heterosexual transmissibility, and not through the previously recognized high risk group interactions. I would not be at all surprised if in this country we will be seeing an increase in the relative proportion.

In other countries, including several in Africa, it is quite clear that a significant amount of transmission is by heterosexual contact. So the potential clearly exists for heterosexual transmission in the United States, and I think that this will be a problem.

Senator WEICKER. Bill, what I have done, we have before us the National Cancer Institute, and Dr. DeVita. But in order to coordinate the focus on the matter of AIDS, and Dr. Fauci is responsible for the coordination at NIH, he joined Dr. DeVita.

Right now, the subject is AIDS, period. As soon as you are through with any questions that you have, then I am going to excuse Dr. Fauci, and we will continue with the National Cancer Institute.

I might add, while Senator Proxmire asks his questions, I will depart a little bit from procedure but only because I believe that dissemination of knowledge is so important. If there is any member of the press who has any questions that have not been responded to here in the course of the questioning, if you will submit it to me in writing, I will see to it that it is answered because I can't think of a better forum to get the answers out to the public.

AIDS—PROJECTION OF NUMBER OF VICTIMS

Senator PROXMIRE. Dr. Fauci, let me just ask you two questions that are directly related to that brief.

In your prepared statement, I understand, you estimate that more than 1 million Americans have already been infected by AIDS, and approximately 10 percent of these will develop clinical AIDS within a 3-year period.

Can you give us any idea of the long-range outlook for these many Americans? What percentage do you expect to contract full-blown AIDS over a 5- or 10-year period?

Dr. FAUCI. We do not know, but there are, as I am sure you are aware, Senator, speculations. There is one study from New York City that shows that up to 30 percent of individuals, within a 4-year or so period, will go on to develop full-blown AIDS.

The 10-percent figure that I gave is based on statistics from a number of centers showing that there is a 3-percent increase per year. The real question is, are we going to see a curve that continues to go up or are we going to see a plateau? There have been a variety of projections.

I would not expect, given the nature of this virus, and in some respects its similarity to another virus, with which large numbers of the population in a certain section in Japan are infected, that 50 years from now we are going to see 95 percent of those infected people getting the full-blown disease. But I would not be surprised, if after 10 or 20 years, we do see 30 to 35 percent of those individuals with full-blown disease, which would amount to hundreds of thousands of people.

Senator PROXMIRE. After how many years?

Dr. FAUCI. Over a period of 10 or so years.

Senator PROXMIRE. I see. Over 5 or 10 years 30 percent of the 1 million carrying the virus could get AIDS—about 300,000 people.

How many more Americans do you estimate will be infected with the AIDS virus over the next 3 to 5 years?

Dr. FAUCI. That is very difficult to determine. Given the fact that there are approximately 1 million individuals already infected, I think if there is a total disregard for the fact that an asymptomatic virus carrier can infect someone by sexual contact, there could be a virtual explosion. But there are early indications of the recognition by the risk groups, of the danger of the kinds of sexual activities, particularly large numbers of sexual partners, which had gone on prior to the realization of the scope of the syndrome. Therefore, I would think that we are going to be seeing a leveling off. But even if it does level off, we are still talking about a doubling or a tripling of the number.

Senator PROXMIRE. Thank you, Mr. Chairman.

Senator WEICKER. Thank you very much, Senator Proxmire.

There might be further questions from other members of the committee on this subject, they will be submitted for response to the record.

SEQUESTRATION AND RESCISSION

Dr. DeVita, how has that initial cut impacted upon your Institute? Was there an additional cut taken in the 1987 fiscal year budget as far as your Institute is concerned?

Dr. DEVITA. As a result of sequestration, we took the 4.3-percent reduction from each of the budget categories within the Institute equally, Senator. There was an additional rescission of $6.8 million. This leaves us with the revised budget of $1,170,000,000, and the 1987 budget is $1,158,000,000, or $12.4 million less than the revised 1986 budget.

Senator WEICKER. How much less?

Dr. DEVITA. It is $12.4 million less.

Senator WEICKER. I gather that the proposal, and its specific figures in 1987, reduces your budget by $66,207,000 under fiscal year 1986 appropriated levels.

Dr. DEVITA. Yes.

Senator WEICKER. Can you give us some idea of the impact of these reductions on the kinds of research that would be stopped or lost?

Dr. DEVITA. Of course, as Dr. Wyngaarden mentioned, we had to readjust our priorities as we usually do, and continued to support the very high priority areas with increases, and some areas that are less exciting at the moment got some reductions.

For example, we are going ahead with the LAK Cell Program at full speed, and the Drug Development Program in AIDS at full speed. Some of the other areas that I mentioned in my opening statement, for example, clinical trials, will go ahead at the current level. It is a matter of readjusting to meet those priorities.

SALARY LEVELS

Senator WEICKER. One last question before I turn it over to Senator Proxmire.

Again, you have contact with various academic institutions and those young people who are graduating from those institutions, et cetera. Between this budget cutting process, and the really top moneys that the pharmaceutical firms pay, especially with all of the new genetic engineering, is it difficult to attract good young people to this business of research?

Dr. DEVITA. It is a very difficult question to answer. I don't think that there is an automatic, it is getting more difficult to attract them. Research is getting more and more exciting, so the opportunities are terrific, and lots of young people want to go into biological research.

However, the biotechnology industry is, in fact, drawing people away from us. We are being raided constantly at NIH in the intramural program by the biotech industry, but these are persons a little bit further on in their careers. That would have happened, of course, under any circumstance because we are a great source of young talent.

There are some people who don't want to go into that kind of research because it requires that there be a product at the end of the line, and many people want to delve around and search for knowledge for the sake of knowledge, and we are a much better place to do that than anywhere in the world. So we have some people who stay in spite of all indications that they should leave—larger salaries offered to them, opportunities that seem beyond what we can offer.

Dr. Rosenberg, I believe, is a good example. He is a surgeon who can command triple his current salary, triple his resources, and so forth, yet he stays where he is. He is the discover of the LAK cell therapy that I mentioned earlier.

Senator WEICKER. He works within your Institute?

Dr. DEVITA. He is the chief of our surgery branch.

Senator WEICKER. How much does Dr. Rosenberg earn?

Dr. DEVITA. About $70,000 a year, I would say.

Senator WEICKER. How much do you earn?

Dr. DEVITA. About $80,000, or something like that.

Senator WEICKER. How long have you been there?

Dr. DEVITA. Twenty years.

Senator WEICKER. Why do you stay?

Dr. DEVITA. It is the most exciting place in the world. It is not given to too many people to have the opportunity to manage a program like the Cancer Institute. I have been involved in this program at the branch level doing my own research, through division director, and Institute director. I am totally committed to the Institute. I am quite certain that through the cancer program, before the end of my days, there will be a radical departure from the current incidence and mortality figures that we see. It is hard to beat the excitement associated with that anywhere else.

Senator WEICKER. What will happen, with this Gramm-Rudman cut, vis-a-vis people's salaries; does it impact on those?

Dr. WYNGAARDEN. Not on individual salaries. It would be total resources that are affected, and we will have fewer people.

The initial impact is primarily on those things that are controllable, expendables in the laboratories. In time, it will be reflected in fewer people.

Senator WEICKER. You, obviously, have knowledge of this because you oversee the whole, how much would men like Dr. DeVita and Dr. Rosenberg make with a topnotch pharmaceutical company?

Dr. WYNGAARDEN. I don't really know, with pharmaceutical companies, but I am sure that they would double or triple their current salary. In a university, the chairman of a major clinical department would be paid about double what Dr. DeVita has quoted you.

Senator WEICKER. I just find it absolutely appalling, with what is being paid to various and sundry professions in the trade, in sports, entertainment, and all the rest, that you are working for $70,000.

Dr. DEVITA. I can't shoot baskets. [General laughter.]

Senator WEICKER. I might add, I feel the same way about my own salary.

Senator Proxmire.

Senator PROXMIRE. Just think of how you might do as a utility infielder with the Mets. You could be making $250,000. [General laughter.]

But it wouldn't be as exciting. I think that was a marvellously reassuring answer. Then, of course, the prospects of improving the chances of people surviving cancer, or avoiding cancer, are very exciting indeed.

FORMALDEHYDE STUDY

Your Institute, Dr. DeVita, recently came out with a study indicating that there is little evidence that formaldehyde causes cancer among workers. That study has been criticized on at least two grounds. First, Frank N. Myer, the director of the United Auto Workers Health and Safety Department, was quoted in the New York Times as saying, "Investigators reconstructed workers' exposure to formaldehyde based in part on some subjective judgments, not on what exposure was in the past. They did not have historical data."

Is that a fair criticism?

Dr. DEVITA. No; because they did reconstruct objectively. They took levels of formaldehyde exposure they had and could measure now, and they went back and looked at working conditions over the years of the study, and they made the best estimate they could possibly make on exposure levels at those times. Sometimes, they had accurate measurements.

I think the major point is that there is no other way of getting any more accurate data than they had.

By the way, Senator, the study just says that under the conditions of the study, that formaldehyde does not seem to produce a large excess in numbers of cancers. There are one or two subsets that are being studied further.

We know that formaldehyde produces cancer in rats, so it is very likely that it is an animal carcinogen, and with big enough exposure in humans probably would cause some cancers.

It is reassuring that a study of this size, with 26,000 people, can't identify a large excess, or even a significant excess of cancer.

Senator PROXMIRE. Wasn't there any historical data available?

Dr. DEVITA. Yes; in fact, most of the study was based on going back and getting historical data.

Senator PROXMIRE. Then the statement by Mr. Myer is not correct.

Dr. DEVITA. I don't think that it is entirely accurate.

Senator PROXMIRE. The study has also been criticized because of the participation of several industry scientists, raising the possibility of a conflict of interest. What is your response to that objection?

Dr. DEVITA. We did the study. We selected the hospitals. We selected the data, and we wrote the paper. The industry scientists were very helpful, when we needed to get certain kinds of data for the study, they provided access to the data. It is customary, when preparing scientific manuscripts to make sure that the people who played a significant role in the study are recognized on the paper.

One could say it might have been wiser not to do it so we wouldn't be criticized, but it is really kind of unfair to the people who assisted by providing access to the data.

The basic point is that the Cancer Institute had total control over that study, and we were not influenced in any way by anybody from industry, including the Formaldehyde Institute which played a role at the beginning of the study.

Senator PROXMIRE. In late January of this year, I received a letter from a member of the University of Wisconsin's Department of Biochemistry, Dr. Alfred Harper. Dr. Harper was very critical of a memorandum from Dr. Peter Greenwald of your staff.

The memorandum referred to a report of a group chaired by Dr. Harper as "the fiasco of 1980 known as the 'Toward Heathful Diets' paper." In doing so, it was quoting an article appearing in Science magazine.

Dr. Greenwald was referring to Dr. Harper's participation in a nutrition symposium and recommending that there be more balance. I have no problem with such a recommendation. However, I would like to get your thoughts on what Dr. Harper feels were ad homimem attacks on his work by Dr. Greenwald.

Dr. DEVITA. I have corresponded with Dr. Harper. Dr. Greenwald spoke to him directly last week at a meeting in Washington.

I believe they have smoothed out any differences. I don't mean this to be glib, but I am a little amused by the nutrition field. I am not a nutritionist; however, I had something to do with changing the Institute's policy on research in nutrition 5 years ago.

We have done a lot and we are proud of it, but the more you do, the more controversy you generate because within the nutrition field there are people who feel very strongly about subsegments of it. When they criticize each other this kind of situation arises.

I don't view this as being very serious, and I think that it has been settled. It is a matter of whether you believe that fat is a more important influence than fiber, or energy expenditure, or certain micronutrients are more important than either one, and whether or not you have enough data to say anything at all about diet. I believe there are enough data to make recommendations and that is my particular problem.

Senator PROXMIRE. Apparently, Dr. Artemis Simopoulous, chairperson of NIH's nutrition coordinating committee, played a major role in the planning of the symposium. This was considered by some as being a conflict of interest.

Have you taken any steps to clarify the extent to which it is proper for NIH personnel to participate in the organization of outside conferences, especially conferences that appear to be sponsored by industry-backed groups?

Dr. DEVITA. We always look at that, but perhaps Dr. Wyngaarden would like to answer that with respect to Dr. Simopoulous.

Dr. WYNGAARDEN. Yes; we have a clearance mechanism for participation of intramural scientists in all projects of that sort. We did not feel that there was a conflict of interest in the role which she played. There were many, many people who participated in the planning of conferences.

Senator PROXMIRE. Was she paid by industry?

Dr. WYNGAARDEN. No.

Senator PROXMIRE. She was not.

Dr. WYNGAARDEN. No; her participation is in terms of conferences, or in terms of scientific review, and not in terms of policy of industry, or policy of outside groups.

CLINICAL TRIAL OF BREAST CANCER TREATMENT

Senator PROXMIRE. The NIH justifications cite a clinical trial of breast cancer treatment demonstrating that less disfiguring surgery, segmental mastectomy, followed by radiation is as effective as the removal of the entire breast for many women in the early stages of breast cancer.

Can you tell us what percentage of mastectomies are now segmental, and how that percentage has changed over the last year or so as the result of your clinical trial?

Dr. DEVITA. At the time that we had this conference, which was last September, we had figures that of the total numbers of breast operations about 15 percent were segmental. The rest were all modified radicals, or total mastectomies. We do not have any data since that time. We will be following this area. We do have mechanisms for getting that kind of information.

Senator PROXMIRE. So you will have that data at some future date.

Dr. DEVITA. We will look at it next year when we put together the annual surveillance epidemiology and end results [SEER] report. We can look at treatment applications. We, of course, are very hopeful that the very wide recognition of that particular study, including the fact that the person who published it just received the prestigious Lasker Award for his work will, in fact, highlight the importance of it, and lead to the use of more segmental mastectomies.

REDIRECTION OF FUNDS

Senator PROXMIRE. Last year, in a response submitted for the hearing record, you indicated that in fiscal year 1985 funds were redirected from cancer biology research to cause and prevention research because of the development of a significant new research program on oncogene research and carcinogen induced mutagenesis.

Has there been any comparable redirection of funds in fiscal year 1986?

Dr. DEVITA. Not yet, Senator. We will have some reprogramming requests because, as I indicated in my opening statement, there are some things that are happening that are really quite exciting that require we move resources around. Again, I go back to the interleukin-2 and LAK cell project which went from an intramural study to a national study in a very short period of time. We had to move resources around quickly to do that. We hope we continue to have the need to do that kind of swift application of new findings.

Senator WEICKER. Senator Andrews.

INVESTMENT IN BASIC BIOLOGY

Senator ANDREWS. Thank you, Mr. Chairman.

It is good to be here. I just came from chairing a hearing on transportation, and listened to the Administrator of the Federal Highway System point out that we had to sustain considerable cuts in order to meet our budget targets. I pointed out that after all highway construction is an investment in the future of this country, and not a spending program. Instead of targeting in on 21 percent of Government spending, we should have an across-the-board freeze so that the investment programs would be protected—education, health care, NIH.

I look at your budget justification, doctor, and I see that you look on it as an investment. I saw that word that you used in your justification book saying that the justification for the National Cancer Institute states, "The investment in basic biology is the result of the development of major new technology that allows scientists to put knowledge to work." We salute you for it. We think that you are beginning to get a little practical politics into your justification books, and maybe it will help us do our job up here.

I think the people back in North Dakota have been proud of what you are doing. The National Cancer Institute developed a new approach to cancer treatment, and we saw progress also in other areas, such as the identification of genetic markers for cystic fibrosis.

I want to assure the chairman that I intend to work with him in a joint effort to see that NIH continues to be recognized as the finest research facility not only in this country, but in the world, not because it is a spending program, it isn't, but because, precisely, it is an investment in the future of our country, and we are pleased with what you are doing.

INTERNATIONAL FOOD COMPOSITION DATA SYSTEM

I would also like to get to a very specific question. In your Cancer Institute, doctor. Years ago, when I was in the other body, I was concerned because we seemed, at the Department of Agriculture, to know more about pig nutrition than we knew about people nutrition. Actually, when you get right down to it, people nutrition is a heck of a lot more important than pig nutrition, important though livestock knowledge is.

We put together, then, human nutrition laboratories, the first one, by some strange coincidence, since I sat on the Agriculture Appropriations Subcommittee, was located in North Dakota, in Grand Fork. We have found a number of intriguing things in the field of nutrition. Later on, there has been one at Tufts, and one down at Baylor, and they are putting out considerable information.

We just heard you mention a moment ago the importance of knowing about nutrition. I was glad to learn that your Cancer Institute is developing an international food composition data system. I am hopeful that this data system will provide the needed information for formulation of policy on nutrition related health issues.

When can we expect this system to be ready?

Dr. DEVITA. It is partly operational. I am glad you brought it up, Senator, because actually we are working very closely with the Department of Agriculture at Beltsville. One of the impediments for doing prospective studies to prevent cancer using nutritional factors, micronutrients or macronutrients, has been just what you said. We may know more details about pig nutrition than human nutrition. We don't know what the components are in human diets, so we cannot analyze retrospectively what kind of diet someone ate in order to link diet to future events.

The unit in Beltsville, which may be a spinoff of the units that you mentioned, has the capacity to make these kinds of analyses, and they are working very closely with us to standardize analysis of food components. We also have part of the international system set up. Most of our data on what role diet plays in the prevention of cancer comes from migration studies from one country to another. It is very important to be able to go back and tell what it is that people actually ate, what kind of fiber they eat, what components are protective, what components of fat are promoting, and so forth.

HUMAN NUTRITION STUDIES

There has been some very interesting work lately from England, focusing on two components of fiber, and then looking at colon cancer mortality in England. It shows a much stronger association of the intake of these specific types of fiber, for example, with reduction in mortality from colon cancer.

We are zeroing in as a result of those kinds of efforts. But there is a real impediment to start these studies.

Senator ANDREWS. I can remember an almost accidental finding that we had in Grand Forks. They were doing work on fiber, and they were using carrot fiber and celery fiber, and all kinds of other fibers. Since we produce hard spring wheat, they also used some spring wheat bran, and they found out that that spring wheat bran, not only does all the other good things that fiber does, but sharply reduces cholesterol.

They wanted another floor in their laboratory, and Mary and I were up there, and we thought that maybe this was another of those whizz-bang stories, but they seemed convinced. So we got some bran from our experiment station, and Mary whipped up some recipe for bran muffins. We ate a couple, and we went around. This was a year or two ago, but it works.

In fact, a couple of Senators on this committee are using those bran muffins, and it sharply reduces cholesterol, if you eat a couple of them three or four times a week. It works. That is why I am a believer in the fact that human nutrition could be a key method of solving some of these problems, cancer, heart disease, and the rest.

That is why I am intrigued with your saying that you are beginning, in greater depth, the study of human nutrition as a causative agent to these dread diseases.

You think that these results will be on line in a matter of months?

Dr. DEVITA. Well, it depends. We are starting a large study called the woman's health study, which studies the reduction of fat intake of the study population from 40 percent of calories from fat to 20 percent of calories from fat, because that is the leading hypothesis in reference to diet and the etiology of breast cancer. We have two views. One is that it will take 10 years for us to reduce the incidence of breast cancer. The other view looks at data that came from Great Britain during the war, which shows that within 3 years we began to see a decrease in the mortality from breast cancer when the British had to change how they distributed certain kinds of food during the war.

In order to set the study up, we have assumed the most conservative estimate of 10 years, but it is possible that we will see it before 5 years.

We have another large study going on in this country with 22,000 physicians, jointly with the Heart Institute, to examine prevention of heart disease with aspirin, and cancer with beta carotene, which could give us data in 4 years, but might take as long as 10 years.

No one is quite sure, when you intervene, just how quickly you will see a positive result, but you have to start sometime.

Senator WEICKER. My father, when he came home from World War II, he was in the 8th Air Force, said that he never cared if he saw another brussel sprout as long as he lived. He said that is all there was in Great Britain.

Dr. DEVITA. They were short of flour, so they put the millings back into the flour. In doing so they also increased the fiber intake in Great Britain to a great degree. Then, of course, they were short of meat, so the fat intake went down. What you saw was a great decline in mortality from breast cancer and colon cancer within 3 years, and it took 10 years for it to come back up to the prewar level.

That is a nice way for change to happen. It comes down quickly, and it takes long to go back up, and that is what we are generally shooting for. But we have the study set up on a conservative estimate, just in case, because you don't want to drop the study too soon, before you get the information.

PREVENTION AWARENESS PROGRAM

Senator ANDREWS. Doctor, given these findings that you are in the process of broadening, given also the fact that we have a host of knowledge already assembled, how do we get this disseminated?

I mentioned hard spring wheat bran and its effect on cholesterol. There is also a vast difference in cooking oil. Sunflower oil is a far better source of cooking oil than coconut oil or palm oil, and even some of the other oils that we use more generally in this country. How do we get that information out?

How do we then insist on labeling so that the consumer who has the time to study these technical manuals, or the consumer whose doctor studies these technical manuals and suggests a switch to sunflower oil, or some hard spring wheat bran, or some of these other things that you are developing that would be helpful for them?

How can the consumers have the ability to pick and choose in an accurate fashion these different components of their nutrition system that will be helpful to them?

Dr. DEVITA. Here is where I g[illegible] in a little trouble. I was just telling Senator Proxmire.

In 1980, we started this prevention program that included research on the role of diet. By 1982, we realized that as we were doing business in public, including coming to these hearings and talking about these things, the public starts to ask questions about what we are doing. So we developed a Prevention Awareness Program, which was announced by Secretary Heckler in 1984, which included recommendations we thought were reasonable based on our data and the National Academy of Sciences report with reference to fat and fiber, particularly.

We have, in fact, distributed—I have brought it with me—this booklet which gives you information that I think you are looking for. We made wide distribution of that booklet, and we do answer questions in reference to the points that you made.

The recommendations also serve as our umbrella under which we do the studies that I have mentioned. We are recommending to people that they lower their fat intake, for example, but at the same time we are studying low fat intake in terms of its ability to prevent cancer. It seems like a contradiction, but it is not. We need to know more specifics about how low you go, and what component of the diet is important in reducing cancer incidence.

It causes some public concern. We are criticized for saying too much, if we say much of anything and we are criticized for saying too little, if we say nothing. We hope that we strike the proper balance.

Senator ANDREWS. Thank you very much for your candor, and for the great work that you are doing.

Let me again assure the chairman that I am going to work with him in our joint effort to see that we treat your funds as investment funds, and we make sure that they are disseminated in the best possible way so that people can begin benefiting from them by having that information on hand.

Dr. DEVITA. Thank you, Senator.

HEALTHIER FOODS

Senator WEICKER. Thank you very much, Senator Andrews.

I imagine that one of the things that you are going to run into, every State produces different things. You have heard now from hard spring wheat and sunflowers.

Senator ANDREWS. If you want to lower your cholesterol, come to see me.

Dr. DEVITA. May I comment on that? I was just talking to Dr. Lenfant about this when we came in, and both of us have the same experience.

We are working very closely with the meat institute, for example, and as far as they are concerned, they can produce whatever the American

people want to eat, and the American people want to eat leaner products. They are not at all unhappy with what we are doing, they are rather pleased. I understand that Dr. Lenfant has had a similar experience with the egg board.

So we are not having as much trouble as we thought we would have to begin with, partly because the American people are very health conscious, and they want these things to happen, and people want to sell their products. In a sense, they are looking to us for some guidelines as to what they can do to make healthier foods.

Senator ANDREWS. He is doing us a service. In my honest living, I feed those four-legged losers out there in the field. Let me tell you, it costs twice as much to put 1 pound of gain between 1,100 pounds and 1,200 pounds as it does to put 1 pound of gain on between 700 and 900 pounds. So it is not only more healthy not to get that wasteful, fatty beef product on the beef counter, but it is a whale of a lot more cost effective for us. But we don't get paid on that basis because until the public realizes that this is a desirable product, and one that they want, they are not going to buy it.

They go in there, and if they don't have that bark, and they don't have marbling, and all of the rest, they say, we don't want it. Taking an old critter and mistreating it and all, you can fatten it up, and it has loosened muscle like we get when we don't get enough exercise, and it is kind of tender. But you get a young calf and you feed it the right ration, you can get it tender at weight 1,040 or so, and you don't have all of the problems that you mentioned, and it is more cost effective for the farmer.

So anything that you can do to speed up that kind of work, pointing out that beef is nutritious when it is fed properly, we are going to applaud you for it.

Dr. DEVITA. Thank you, sir. It is a little bit out of my line, but I will try.

Senator ANDREWS. You are doing well, doctor, you keep right on doing it, and farmers will support you.

INTERLEUKIN-2 AND LAK CELLS

Senator WEICKER. One last question before I let you go, and there are other questions for response to the record.

Your work in interleukin-2, is there adequate funds available for you to continue that?

Dr. DEVITA. We are going to have to shift resources around, Senator. I would tell you that in my judgment, we may see the end of kidney cancer as a killer. We have not seen a failure yet in kidney cancer with interleukin-2 and LAK cells. We now have the six centers set up to confirm that observation, among others, and if that continues, we very likely will have to expand the studies in interleukin-2 and LAK cells to include all people who are operated on for kidney cancer and have a risk of getting it back. We are not too far behind in melanoma. The results are really quite exciting.

As of this morning, we had 71 patients treated on the protocol, 49 of whom have been fully evaluated. We are adjusting it day to day depending on how difficult it is to give. For example, we have a couple of patients who have responded while they are being given corticosteroids along with the program. We were worried that this could abrogate the response rate because it takes away the side effects. It turns out that we are getting a few responses with the steroids that indicate that the interleukin-2 program might be much more simple to do 1 month from now, or 2 months from now. So it is changing on a week-by-week basis.

REPROGRAMMING RESOURCES

Senator WEICKER. Why should you have to shift resources when you are obviously going down a very promising path?

Why shouldn't you be able to come to us and say, this is what we need to continue down this path?

I don't understand that, and I would like to know what is needed without your having to shift resources. I think I know this budget as well as anybody else does, and between Jim's able administration, and each one of you at the head of the institutes, and this committee, I don't think that there is any fat in this budget, and there hasn't been for a long time. It is not a question of the fact that we have a lot of stuff out there that we can shift around.

If you are shifting resources, it is coming out of something else that is pretty valuable. That is the only way that I can see that.

Dr. DEVITA. Well, Senator, when the budget is settled, and we have the budget in our hands, our problem is how to get the maximum bang for the buck. We are committed to make sure that the highest priority programs get the dollars, and that takes a certain amount of flexibility. That is our primary concern at whatever budget level we get.

In all fairness to the President's budget, and you have heard me say this before, I was managing this budget in 1980, when we first hit $1 billion, and with inflation going the way it was, we were dead in the water. We couldn't move money around fast enough to take advantage of the opportunity.

So it is a little easier now, with inflation at a much lower level, for us to make the ends meet within the budget level.

What I am really saying is that I need as much flexibility as I can possibly get within a given budget level in order to take advantage of the opportunities that are there.

Senator WEICKER. As I said, on the inflation, I think we all give the President great credit in terms of his economic policies. As far as your money is concerned, you can thank this committee, and not the President.

Dr. DEVITA. Yes; and we are grateful for your interest.

Senator WEICKER. We can share a little bit of the credit all around here.

I still hear you saying to me that you have to shift some resources so that you can proceed satisfactorily down this path vis-a-vis inter-

leukin-2. My question is, why do you have to go ahead and shift your resources?

I would appreciate it if you would submit to the committee a separate standing item as to what you think you need vis-a-vis going ahead in pursuing this particular program.

[The information follows:]

REQUIREMENTS FOR INTERLEUKIN-2 LAK NATIONAL TRIALS

The interleukin-2 LAK treatment costs an average of $40,000 per patient. This cost will vary with each patient's response to therapy and the number of cycles of therapy required. The primary component of these costs is patient care, including hospital-bed costs, which also vary geographically. It should be noted that changing technology may influence the cost of this investigational treatment. Therefore, approximately $20 million would support a national trial of 500 patients.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. We have further questions for response to the record.

I will tell you what I am going to do because, obviously, we are running over time. I am going to take NIAID, we will do that this morning.

Very frankly, I don't want to rush over the National Institute of Aging, that is too important from my perception, nor indeed the Research Resource Program. What I am going to do is, tomorrow is a blank day because I was going to be out of town, I am not going to be out of town, and we will handle NIA and research resources tomorrow morning at 10 o'clock. We will finish with the infectious diseases this morning.

Thank you very much, Dr. DeVita.

Dr. DEVITA. Thank you, Senator.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

Question. If the automatic provisions of Gramm-Rudman-Hollings are triggered in FY 1987, your Institute may well have its budget reduced by 20 to 25 percent. Have you prepared a contingency plan in the event Gramm-Rudman-Hollings becomes reality?

Answer. The request for FY 1987 was formulated within overall levels designed to contain the Federal deficit within the limits prescribed by Gramm-Rudman-Hollings. Because of this, we have not developed any plans to reduce our 1987 budget below the levels contained in the President's request.

Question. If cuts of this magnitude become reality, how will they be distributed:

1. Intramural versus Extramural Programs;
2. Peer Review System;
   Would the number of site visits be reduced?
   Would travel to NIH to study section meetings be affected?
3. Would NIH employees have to be furloughed?
4. What major programs would have to be cut back?

Answer. We do not anticipate that further reductions will be necessary because the 1987 budget was developed in the context of Gramm-Rudman-Hollings. However, if further reductions are in fact necessary, we would take the reductions by protecting those most promising areas of research, while at the same time de-emphasizing or phasing-out other programs. Until a full review of all programs and activities is completed it is not possible to identify those which would be cut at the levels you mentioned. Undoubtedly, though, program areas affected would include those supported extramurally through Clinical Cooperative groups, cancer centers and research contracts. In addition, intramural research efforts would be slowed.

When we effect a change in the budget, we try to distribute the change in a manner that will allow the most efficient use of resources. Because cancer research is progressing so rapidly on many fronts - basic cancer biology, detection, diagnosis and treatment research, and preventive and control research - great opportunity exists in all areas. We make every attempt to distribute resources in a manner commensurate with the opportunity that exists in each. Because of this, budget reductions would fall upon all major program areas; within these major areas, reductions would be made in a manner to adequately support those of the highest priority.

Question. Please list the research programs of the highest priority that should not be cut and why.

Answer. High priority basic research which is supported primarily through research project grants and NCI's intramural program will continue, as will clinical research supported through cancer prevention and treatment trials. Other mechanisms, e.g., cancer centers and research contracts will continue to provide essential support to the research community. All of these

mechanisms are important to the cancer continuum. The Institute will make every effort to achieve a balance between available funds and the financial requirements of the best available research which holds promise of bettering the health of our nation.

NEW CANCER THERAPY: INTERLEUKIN-2

Question. In December 1985 there was extensive media coverage of a new cancer therapy involving the stimulation of the body's immune system against cancer and the involvement of a natural substance, Interleukin-2. How long ago did the basic research describing Interleukin-2 take place?

Answer. Interleukin-2 (IL-2 or T-cell growth factor) was first discovered by Dr. Robert Gallo of the National Cancer Institute in 1976. Over the ensuing years, work was devoted to purifying human IL-2 and looking at its effects on the immune system in animals. In 1983, the DNA sequence was determined and IL-2 was purified by gene cloning techniques.

Dr. Steven Rosenberg's laboratory at NCI has been attempting to develop new techniques for immunotherapy of human cancer since 1977. Major efforts in the past to develop immunotherapies based on non-specific stimulations of the body immune system used substances such as BCG, C-parvum, and levamisole in the hope that the general increase in the immune reactivity would lead to an increase in the immunoresponse against a tumor. This non-specific approach has been largely unsuccessful in humans.

In 1980, researchers in Dr. Rosenberg's laboratory noted that the incubation of lymphocytes in IL-2 resulted in the generation of cells that were capable of destroying fresh tumor cells but did not kill normal target cells. Over the ensuing years this discovery was tested in various animal tumor models such as adenocarcinoma of the colon, esophagus, sarcomas, adrenal gland carcinomas and pancreas tumors. In the early 1980s these experiments were difficult to do because it was difficult to obtain pure IL-2 in any significant quantity. However, in 1983 when the DNA sequence of the gene coding for IL-2 was determined by Dr. Tanaguchi and co-workers, recombinant IL-2 became available in virtually unlimited supply. Dr. Rosenberg carried out multiple experiments and the results of 44 experiments performed showed a consistent 90 to 95 percent reduction in the number of metastases in animals. After testing this in various tumor types including melanoma, renal cell carcinoma and colon adenocarcinoma in animals, Dr. Rosenberg in 1984 began a Phase I study which tested the administration of LAK cells which were generated with IL-2 in humans and showed that they could safely be administered. Additionally, the maximum tolerated dose of IL-2 in humans was established.

Question. Do you know yet if this therapy will be effective against all cancer?

Answer. No. We do not know yet if this therapy will be effective in all cancers. We do know that it has been effective in patients with colorectal carcinoma, melanoma, renal cell carcinoma and adenocarcinoma in the lung. It has also been tested in esophagea carcinoma, gastrinoma and ovarian carcinoma and has not

yet been successful as yet. Animal studies have suggested that this therapy is most effective against small amounts of disease and thus the potential use of this therapy in cancer patients that are at high risk for spread of their tumors, i.e., metastases is a very exciting possibility.

Question. How effective has it been so far?

Answer. As of February 20, 1986, NCI had treated 49 patients with Interleukin and LAK. Of these, 18 patients -- 37 percent -- had a clinical response which is defined as the resolution of at least 50 percent of the tumor burden. Two of the patients, one with melanoma and one with colon carcinoma, had a complete response. Therapy has been most effective in colorectal carcinoma in which four out of 15 patients have responded, melanoma with five out of 12 responding, and renal cell carcinoma where eight out of eight patients have responded. An additional six patients have received therapy in the Biological Response Modifiers Program unit at the Frederick Cancer Research Facility. Two of these six patients are too early in their treatment to evaluate, but three of the four evaluable patients have responded. One patient with metastatic melanoma had resolution of her lung lesion and is presently free of disease.

A patient with renal cell carcinoma has had a response in bone and lung lesions. A patient with lymphoma has had shrinkage of lymph nodes.

Question. I understand that other institutions are now receiving funds to test this new therapy. How many do you plan to fund, and is this enough?

Answer. In response to intense public interest in this new treatment, the NCI invited cancer research institutions to submit proposals for clinical trials that would use this immunotherapy approach to confirm Dr. Rosenberg's findings. Six institutions were chosen to be funded through the Cancer Therapy Evaluation Program, including Tufts University (New England Medical Center); Montefiore Medical Center of the Albert Einstein College of Medicine; Loyola University Medical Center in Chicago; University of Texas Health Science Center in San Antonio; the Cancer Research Institute of the Medical Center at the University of California at San Francisco; and the City of Hope National Medical Center. We plan to fund these institutions at approximately $500,000 each over the next year. It is hoped that 240 patients will be treated by these centers and that this number of patients will be adequate for a confirmation of Dr. Rosenberg's findings. As clinical trials with experimental approaches may be accompanied by significant treatment side effects, it is important to monitor this type of treatment scientifically in a clinical trial. However, if the effectiveness of this therapy is confirmed and the toxicity is found to be within tolerable limits, six centers will not be adequate to meet the demands of the number of patients in the United States who might be eligible for this treatment. In 1984, over 190,000 persons had either colorectal carcinoma, renal cell carcinoma, melanoma or adenocarcinoma of the lung and it is these four cancers which have shown the best response to this therapy so far. There were 100,000 deaths caused by these types of cancers in 1984. The current IL-2/LAK therapy is very manpower consuming and

expensive, thus additional resources would need to be directed to this area if a technologic/scientific breakthrough permits providing treatment to large numbers of patients who might be eligible for this type of therapy.

Additionally, the Biological Response Modifiers Program is supporting a trial at the University of Wisconsin awarded in September of 1985 for $300,054. This trial is examining the use of lower doses of IL-2. All of these funds have been made available through reprogramming from clinical trials that would have evaluated other new chemotherapeutic agents and combination therapies.

Question. How much are you spending on this now, and how much should you be spending in FY 1987?

Answer. NCI is spending $7.1 million on LAK in FY 1986. Plans call for the Institute to spend $8.5 million in FY 1987. If it were determined that this effort should be expanded on a more national basis, additional resources would be needed.

Question. If your budget is cut in FY 1987, could you redirect resources if necessary? Which programs would be tapped to provide these additional resources?

Answer. Dependent on the expanded level required for this Program, the Institute would seek to redirect resources in order to support it. If the budget is cut in FY 1987, a redirection of resources would be possible. Resources have already been redirected for this work from cooperative groups and from the Drug Development Program in order to support extramural trials. In addition, funds have been redirected from the cooperative groups to fund intramural LAK/IL-2 research.

Question. How close are we to a major clinical trial of this new method of treatment?

Answer. We are doing major clinical trials of this new method of treatment at the present time both intramurally and extramurally. The confirmatory trials that are ongoing in the six extramural institutions previously mentioned are Phase II trials of a major proportion. Additionally, in the intramural setting, we are beginning new trials in Dr. Rosenberg's branch specifically directed at the two tumors which are showing the most response, i.e., renal cell carcinoma and melanoma. The Biological Response Modifiers Program is also conducting a major intramural confirmatory clinical trial.

CANCER MORTALITY

Question. NCI has stated that it intends to achieve a 50 percent reduction in the cancer mortality rate by the year 2000. Approximately 20 percent of the strategy is based on prevention; specifically dietary modifications and a reduction in smoking. How would any budget cuts in FY 1987 and in the coming years in your cancer prevention programs affect your goal of a 50 percent reduction in cancer mortality?

Answer. The NCI estimates of a 50 percent reduction in cancer mortality by the year 2000 rests on several fundamental assumptions. First, the decrease in smoking since the publication of the 1965 Surgeon's General Report must be accelerated to a quit rate of approximately six percent per year compared with the more recently determined rate of two percent per year. Further, changes in diet with the adoption of a 30 percent fat diet and an increase in the fiber consumption are also important. Finally, there is an opportunity for improvement in cancer treatment -- specifically, closing the gap between state-of-the-art treatment and current cancer therapy and further improvement in state-of-the-art cancer treatment accelerating the existing trends in cancer survival improvement through treatment gains. We anticipate that this will come from the use of drugs or biologics in the postoperative period where positive leads, if they are confirmed and extended to the population at large could affect as many as 120,000 patients.

The cancer incidence rate in heavy smokers can be 10 to 20 times that of non-smokers and even light smokers. It is now known that the number of heavy smokers (i.e., more than 25 cigarettes per day) is increasing relative to the overall proportion of smokers. In other words, heavy smokers are quitting at a lower rate than the light and moderate smokers. The NCI is planning a major community trial targeted toward heavy smokers and it will be funded consistent with the resources level available.

Further, a major smoking education effort requires a national coordination of activities between NCI, other Federal agencies, the States, and the volunteers in professional societies. This coordination is staff intensive. The level of coordination will, at least in part, be dependent on the level of staff resources available.

Turning to diet, NCI has launched an extensive research program in diet and nutrition aimed at cancer prevention. An array of chemoprevention research activities has been developed to identify and test micronutrients which may reduce cancer incidence.

International epidemiologic studies, as well as a preponderance of experimental data, provide convincing evidence that some 30 to 35 percent of cancer mortality is related to diet. This evidence is sufficiently strong for prudent measures to be taken toward dietary change -- toward dietary fat reduction and an increase in dietary fiber. A major trial of fat reduction and breast cancer incidence is currently undergoing feasibility testing. It provides a critical opportunity to validate an important aspect of the diet cancer hypothesis. Although this trial was specifically aimed at breast cancer, the results will be invaluable in the overall guidance and direction of the prevention program. Should further budget cuts materialize, the trial would be undertaken over a longer period of time.

CANCER CENTERS

Question. Everyone agrees that the Cancer Centers Program is essential to the National Cancer Institute. How many centers are you currently funding, and how many do you anticipate funding in FY 1987?

Answer. Currently, the Institute is funding approximately 57 cancer centers. We plan to fund the same number in FY 1987.

Question. Are you able to fund cancer centers at recommended levels?

Answer. No. The Institute, as in previous years, will not be able to fund centers at recommended levels in FY 1987. It is anticipated that competing centers will be funded at about 22 percent below recommended levels; continuing centers will be funded at about four percent below committed levels. This compares with comparable reductions in recent years.

Question. How are cancer centers funded? Has their budget increased proportionately to the research budget for the NCI? What was your 1987 By-Pass Budget request for the Centers Program?

Answer. As with research project grants, cancer centers are peer-reviewed to evaluate their individual effectiveness relative to overall NCI goals. Cancer centers core grant support from NCI provides for program leadership, centralized research instruments, and facilities not otherwise available through traditional research grants. From the period 1977 to 1985, cancer centers have increased at a greater percentage rate than that of the Institute's total budget. The FY 1987 By-Pass budget for cancer centers was $108 million.

Question. Cancer centers vary greatly in the size and breadth of their total programs. In light of this diversity, how would you adjust to any budget cuts in FY 1987?

Answer. The National Cancer Institute will attempt to fund a total of 57 centers in FY 1987, the same level as FY 1986. To accommodate the projected budget, the Institute will reduce commitments of record for continuing centers and renegotiate new and renewal awards.

Question. Will some of the centers be terminated?

Answer. We will attempt to keep the most productive centers viable in both FY 1986 and FY 1987.

Question. Will each center receive an equal cut?

Answer. No, each center will be reviewed and a cut will be determined based upon the unique circumstances of the particular center.

GRAMM-RUDMAN

Question. NIH has been required to absorb the 4.3 percent ($236 million) Gramm-Rudman cut in FY 1986 by budget mechanism. Does this present problems for the research Institutes or does the lack of flexibility interfere with the Institutes' mission?

Answer. The 4.3 percent cut imposed on the budget of the National Cancer Institute from the Gramm-Rudman-Hollings legislation requires that hard decisions be made amongst competing research priorities. However, we are allowed to redirect under

existing reprogramming rules in order to maximize the country's investment in cancer research.

Question. How much direction and flexibility should the Director of a research Institute have in order to minimize the indiscriminate impact of across-the-board cuts?

Answer. The NIH is an organizational entity comprised of 11 research Institutes whose missions delve into the cure of a myriad of complex diseases. For the Federal government's health research policy it is useful that an overall theme be implemented. However, in my opinion, it is very difficult for any one individual to possess sufficient knowledge to determine the day-to-day adjustments required to manage specific programs. In the cancer field alone, the state of knowledge has never been more dynamic. For an Institute to take advantage of new-found knowledge, it is paramount that some redirection of resources and fine tuning of programs be accomplished rapidly with the assistance of advisors from a broad area of fields. The apparatus to do this on a week-to-week basis is in place at the Institute level. This is especially true in times of reduced resources.

Question. If you had the flexibility to allocate the reductions among your programs in another way, would you shift these funds?

Answer. Given the total amount of the required reductions, some modification of the current distribution could be done. Historically, the NCI has and continues to hold the support of basic research as its highest priority. Since 1976 the funds allocated towards research project grants, that part of the NCI that comprises the largest proportion of basic research, has been increased more than double the growth rate of the total NCI budget. However, other mechanisms also support basic research efforts. Basic research has always been best served by a mixture of support mechanisms. For example, the early work on oncogenes was supported with contracts as was the work using the novel enzyme reverse transcriptase which opened up the DNA recombinant field. Also much of the AIDS effort has been funded through research and development contracts; the fundamental lymphokine activated killer (LAK) cell work was supported primarily through the intramural research program. Yet the confirmation and extension of this LAK work is best accomplished through the extramural research community at cancer center grants and clinical cooperative groups. All of our prevention clinical trials are supported in cancer control grants. The rate of scientific knowledge is exploding in such proportions that it is not always possible to accurately predict very far in advance, the most effective and cost efficient way to fund these efforts, therefore some flexibility in resource allocation is desirable.

Question. Please explain why your choice of distribution would produce better management results?

Answer. As I previously mentioned, scientific research is truly advancing by leaps and bounds. Opportunities for follow-up and further investigation may require a mixture of mechanisms of support including grants, contracts and intramural research and the machinery to make day-to-day scientific decisions too broad for any

small group of people. The outside advisory boards, i.e., the President's Cancer Panel, the National Cancer Advisory Board, each of the four operating divisions' Boards of Scientific Counselors, review and advise on all aspects of the Institute's operations - grant, contract and intramural. This includes modifications and major redirection of scientific endeavors. Coupled with the input of the peer-review advisory bodies, it would be more prudent to adjust and modify programs primarily on their scientific merit and not just their mechanism of support.

IMPACT OF BUDGET REDUCTION

Question. The President's Budget proposal for FY 1987 reduces your budget by $66,207,000 under FY 1986 appropriated levels. Gramm-Rudman-Hollings, if triggered, could reduce your budget even further, maybe as much as 20 percent.

I've known this would reduce the number of grants, possibly the size of grants, centers, training, etc., etc. Can you give us some idea of the impact of these reductions on the kinds of research that would be stopped or lost?

Answer. A 20 percent reduction to our 1987 request would have an appreciable effect upon the pace of cancer research. We would continue to fund our highest priority basic research projects but major reductions would take place in all other programs. Through careful use of remaining resources, we would continue to work towards our goal of reducing cancer mortality by the year 2000 by 50 percent of 1985 rates.

Question. What impact might this have on the health of our citizens five and ten years down the road?

Answer. Although it is difficult to predict with great accuracy the benefits of biomedical research, a major reduction in research funding could be expected to have a measurable impact on the future health of Americans. Both the short-term and long-term impact could be significant depending on the magnitude of the reduction. Programs all along the health research spectrum from basic research -- our major priority -- to clinical research, population-based studies, training, etc. would be affected. While the payoff from basic research is perhaps five to 15 years away, the impact of clinical research can be relatively immediate -- within five years.

Question. Can you discuss your contingency plans if these massive budget cuts should come to pass?

Answer. We do not have contingency plans at this time.

ACQUIRED IMMUNE DEFICIENCY SYNDROME

Question. Last year a portion of the AIDS funding for NCI was provided to the Office of the Director. Has this funding mechanism caused any delay in accessing necessary funds or any delay in your ability to conduct AIDS research expeditiously?

Answer. It is always important to have full responsibility when managing an area -- in this respect, AIDS is no different than

any other area. But AIDS requires a greater degree of coordination and therefore, NCI has submitted a plan to the Office of Director, NIH outlining all efforts in AIDS research. Once the funds are released they are directly obligated for NCI's AIDS efforts.

Question. What impact will the proposal to have all AIDS funding placed in the Office of the Assistant Secretary for Health have on your ability to expedite research and respond to new research findings?

Answer. It is unclear at this early point what practical, operational impact this proposal will have.

AIDS - REPROGRAMMING PROBLEMS

Question. How much money will your Institute receive specifically earmarked for AIDS research in FY 1986?

Answer. Within our FY 1986 appropriation, the Institute has $27.2 million directed towards AIDS efforts, $3.5 million of which was specifically earmarked for AIDS research through an amendment proposed to the 1986 President's Budget and subsequently approved by Congress.

Question. How much money will you spend on AIDS research in FY 1986?

Answer. In 1986, the National Cancer Institute will spend $27.2 million on AIDS research from our appropriation. In addition, we will administer the obligation of $13.5 million appropriated to the NIH Office of the Director for clinical initiatives in AIDS research.

Question. How much of NCI's AIDS research money had to be taken or reprogrammed from other activities, functions or programs?

Answer. It is not possible to estimate precisely the level of resources that have been redirected to AIDS research. Over the years, we have appropriately shifted resources to AIDS as we recognized its importance as a major public health problem.

Question. For the record, please list all activities, functions or programs that were raided for this purpose and describe the specific impact on each.

Answer. In response to the increased research emphasis on AIDS, two major redirection of funds transpired. The first took place within the Laboratory of Tumor Cell Biology headed by Dr. Robert Gallo. That laboratory had been doing substantial work on leukemia biology research. In the past year, the laboratory has redirected nearly all of its attention to that of AIDS and the HTLV-III virus. The second major area is in the NCI Drug Development Program which is charged with developing new chemotherapeutic agents against human cancers. Because of the need to quickly initiate efforts towards the development of new compounds which might be effective against patients suffering from AIDS, the NCI Drug Development Program redirected a significant portion of its attention from cancer chemotherapeutic agents to agents that will hopefully be efficacious against the HTLV-III

virus. This redirection has occurred within both the intramural and extramural elements of the program. Obviously, this redirection of resources within the Drug Development Program will result in fewer compounds being brought to the clinic for evaluation against cancer.

Question. Please provide the Committee with the same information for personnel changes caused by an FTE shortage in the areas of AIDS-related research.

Answer. As AIDS-related research increased during the past year, FTE resources were allocated in three major areas: 1) in the Laboratory of Tumor Cell Biology; 2) in the extramural programs for the development, management and administration of contracts to develop anti-AIDS compounds; and 3) in the clinical area for the clinical testing of promising compounds for AIDS patients. These needs were partially met by the assignment of 20 FTEs to the Institute to meet the needs of the AIDS research effort.

Question. Is AIDS research being done at the expense of cancer programs?

Answer. Had the AIDS problem not surfaced, the $18 million previously identified would have been utilized for other high priority cancer initiatives. The AIDS effort in NCI spans research on etiologic agents and co-factors, epidemiology, drugs for treatment, immunological studies, vaccine development, and animal models of AIDS. These projects have important implications for many other related areas of cancer research.

ACQUIRED IMMUNE DEFICIENCY SYNDROME

Question. I understand that a vaccine against AIDS is in the development stages. Is this true?

Answer. Highly significant progress was recently made in vaccine development against AIDS. The subunit of virus called the major external glycoprotein (gp120) is considered to be a prime candidate for a vaccine. This subunit was isolated in pure form in large amounts. Inoculation of gp120 into a number of animal species, including monkeys, was safe and induced antibodies which were highly desirable, because they killed or neutralized the virus. A second critical property was that the antibodies were also capable of killing HTLV-III-infected cells. The next step will be an attempt to induce like antibody responses in chimpanzees, a species which can be challenged with live HTLV-III. If such induced antibodies prevent initial infection with HTLV-III in chimpanzees, then one could begin to consider responses in man.

Question. How close are we to bringing a vaccine to the testing stage?

Answer. Several major unknowns make a timetable difficult to predict. These unknowns are, first, that one or few variants of HTLV-III would induce neutralizing and protective antibodies against all known isolates of HTLV-III. Second, enough material for a vaccine has to be obtained on a large scale which may be very difficult unless one uses highly sophisticated genetic engineering techniques. Assuming no problems develop, inoculations of

chimpanzees could begin in mid to late 1986. Initial challenge studies with homologous virus would begin in early 1987. By midyear, challenge with other virus types could be attempted. If all indicators show success in preventing HTLV-III-infection in immunized chimpanzees, consideration could be given for Phase I clinical trials with NIAID vaccine evaluation units in early 1988.

Question. Would additional resources enable us to speed up the development, or are we moving as fast as science will allow?

Answer. A number of parallel studies could be initiated using natural gp120 from other virus isolates to determine the spectrum of response. Currently, no promising approach is being ignored; however, quantitative increases are always possible. Increased participation by genetic engineering concerns could expedite candidate products for vaccines. Thus, more diversified larger scale testing could proceed. Additional avenues of vaccine types could be explored and/or expanded, such as a pure immunological approach or the insertion of HTLV-III glycoprotein genes into several harmless viruses. This technique could be very attractive because it could make the vaccine process much easier.

AIDS - TREATMENT

Question. We provided a substantial amount of new funding in FY 1986 for a drug development program for the treatment of AIDS patients. What is the status of this program?

Answer. The program is being directed and coordinated by the National Institute of Allergy and Infectious Diseases (NIAID)/NCI AIDS Drug Selection Committee. This committee is composed of scientists from these two Institutes and it has been given the charge of providing guidance of the AIDS drug development effort. As of March 10, 1986, seven compounds with special promise for treating AIDS patients have been identified and full-scale drug development is in progress for these compounds. Five of these compounds are ready for clinical testing and protocols will be started in August 1986 through the AIDS treatment evaluation units which are being established at this time. It is anticipated that 10 such units will be established in areas that currently experience a high incidence of AIDS. Two of the seven compounds need further preclinical development before clinical testing can be done. These compounds are being given priority over cancer drugs and are being expedited through the drug development system. In addition, several mechanisms are in place in an effort to identify new agents of special promise. These mechanisms are:

1) A drug screening program and anti-retroviral activity which is being coordinated by NIAID which will be able to screen several thousand compounds a year for this activity. Initially compounds in the NCI drug repository will be a major source of material for this screening program.

2) Another mechanism is the National Cooperative Drug Discovery Group mechanism which is coordinated by NCI and is designed to bring the best scientific minds together from various disciplines for the purpose of developing new drugs.

3) A third mechanism is the solicitation of suggestions for the purpose of AIDS treatment and these suggestions are being evaluated by the Drug Selection Committee to determine if any should be entered into full preclinical drug development at this time.

Question. Have you started to spend this new money, and is it speeding up the research?

Answer. As of March 10, 1986 two million dollars were made available for preclinical drug development in AIDS. By using these funds in addition to funds from other ongoing activities we were able to maintain an acceptable level of activity in this area.

THERAPY - ONCOGENE

Question. Your testimony indicates a "startling example of therapy based on oncogene expression". What is this new therapy and what kind of results is it having?

Answer. Advances in cellular and molecular biology have permitted researchers to identify, quantify, and determine the exact molecular sequence of oncogenes in human tumor specimens. While the initial discovery of these tumor-causing genes was an important step forward in determining the cause of cancer in man, it is becoming possible to predict the clinical course and response to treatment of specific classes of human neoplasms on the basis of these findings.

1) Examination of oncogene patterns in patients with the childhood malignancy, neuroblastoma, has allowed investigators at the National Cancer Institute to identify a patient subgroup highly responsive to intensive therapy. Until recently, neuroblastoma was a virtually uniformly fatal disease that responded poorly to conventional chemotherapy or radiotherapy. In examining oncogene patterns in a group of patient with this tumor, it became apparent that a subgroup of patients had an unusual pattern of biochemical and genetic markers quite different from the majority of patients, but similar to the findings in a highly treatable bone tumor, Ewing's sarcoma. When this subgroup of patients (whose tumor is now called neuroepithelioma) were treated with Ewing's type therapy, 14 of 15 cases achieved complete remission.

   This study by Mark Israel and colleagues of the Clinical Oncology Program of the NCI suggests that the elucidation of specific oncogene patterns will provide useful information to the clinician in selecting therapy and in understanding the biochemical and genetic basis for treatment response.

2) A second example of the usefulness of oncogene analysis is forthcoming from recent studies of small cell lung cancer, which comprises 25 percent of all cases of lung cancer in the United States. In this disease, the pattern of oncogene expression has been found to correlate with sensitivity to chemotherapy. Tumors

which contain amplified c-myc oncogenes have been identified by the NCI-Navy Oncology group to be highly resistant to treatment, as compared to the highly responsive tumors which do not contain amplified sequences.

Question. Do you have the funds to expand this experimental therapy to more people and other institutions in FY 1986, or will you have to redirect funds?

Answer. It is our intention to provide the maximum support for work directed toward analyzing patterns of oncogene expression in human tumors. We suspect that this type of analysis of the more common tumors, including breast cancer, ovarian cancer, and acute leukemia, will reveal distinct patterns that separate responders from non-responders, and will help us to understand differences in the clinical course of such patients. Funds may need to be redirected from other programs to support these new studies in the extramural and intramural NCI programs, respectively.

Question. How much is needed in FY 1987, and how much is being requested in your budget submission?

Answer. The findings on neuroblastoma are so recent that we have not had time to determine where they fit in the 1987 budget request.

NEW FINDING

I understand that a recently isolated protein called Angiogenin promotes the formation of blood vessels in tumors.

Question. What can you tell us about this protein and why it is important?

Answer. Angiogenin is the name given to a protein described by Dr. Bert Vallee's group at Harvard which is derived from cultured tumor cells. This protein induces the local growth of new blood vessels when injected into animal tissues. Angiogenin may be one member of a family of natural substances which regulate blood vessel growth. Understanding the factors which regulate blood vessel growth could lead to strategies for inhibiting tumor growth because tumors require the nourishment provided by new blood vessels.

Enclosed is a review from Nature, Volume. 318, Number 7, which more thoroughly describes this protein.

FISH OILS

Question. I am encouraged by the plans of the NIH and the National Oceanic and Atmospheric Administration (NOAA) to coordinate research efforts on the health effects of Omega-3 polyunsaturated fatty acids contained in fish oils. One of the main objectives of the joint conference sponsored by NIH, NOAA, and the National Fisheries Institute last June was to establish a research agenda within NIH to examine this issue. Information presented at the conference indicates that Omega-3 fatty acids play a potential role in the prevention and treatment of a number of

diseases, including cardiovascular diseases and cancer. What is the nature and status of the National Cancer Institute's involvement in Omega-3 fatty acid research, specifically as it relates to fish oils?

Answer. The NCI is interested in the components of fish oils known as Omega-3 fatty acids and their potential for cancer prevention. A concept proposal for a program announcement concerning these fatty acids was considered by the Division of Cancer Etiology Board of Scientific Counselors in February 1986, was approved in open session, and will soon be advertised in the NIH Guide for Grants and Contracts. In addition, in July 1985 the NCI advertised a Request for Applications (RFA) for National Collaborative Chemoprevention projects and dedicated $1.5 million dollars for this funding. (An RFA sets aside money for grants, whereas a program announcement does not.) One application received under this announcement concerns Omega-3 fatty acids and their role in the prevention of cancer and it is currently undergoing review. The NCI Executive Committee has also considered the concept of Omega-3 fatty acids and their potential role in the treatment or prevention of cancer. This committee has asked the Division of Cancer Treatment to evaluate any possible activity that these acids may have in the treatment of cancer. Finally, the NCI is funding a conference grant on dietary fat and fiber in carcinogenesis, which will take place on March 25 and 26. This conference will focus on various fatty acids and types of fiber and their relationship to cancer prevention.

CANCER PREVENTION

Question. What is the Women's Health Study you refer to in your testimony?

Answer. The women's health trial will test whether a low-fat diet (20 percent of calories from fat), compared to the customary American diet (approximately 40 percent of calories from fat) will significantly reduce the incidence of breast cancer among women at increased risk of the disease.

Women eligible for participation are identified from registered cohorts of women, age 45 to 69, and characterized as to their risk factors for breast cancer and their interest in participating in periodic follow-up for early detection of breast cancer. Eligibility criteria include 1) two or more first or second-degree female relatives with a history of breast cancer or 2) more than one of the following characteristics: (a) history or benign breast disease documented by two or more surgical biopsies; (b) history of unilateral breast cancer in one first or second-degree female relative; (c) nulliparous or parous with full-term delivery at age 30 or older; (d) single surgical biopsy with atypical epithelial hyperplasia.

After eligibility and willingness to enter the trial have been established, the women will be randomized into either the nutrition intervention group or the control group by the clinical unit in the ratio of three women to the nutrition intervention group for every two women assigned to control units.

Women in the control group will not be offered a nutrition

intervention program since the general strategy adopted for this group was minimum interference with customary diets while collecting nutritional data considered necessary for appropriate comparison with the nutrition intervention group.

The intervention program for the nutrition intervention group is a nutrition education and counseling approach aimed at providing the women with skills necessary to make a permanent lifestyle change to a low-fat eating plan (20 percent of calories from fat). The general strategy incorporates teaching nutrition skills, self-monitoring techniques, behavior modification techniques, and group support systems.

It is estimated that a study population of 30,000 women with a follow-up period of eight to ten years would be required to obtain a statistically reliable test of the hypothesis. The endpoint is occurrence of histologically diagnosed breast cancer.

Question. Is breast cancer the only cancer that might be prevented through diet? What about colon and others?

Answer. Cancers of 10 sites account for more than 73 percent of all cancer deaths in the U.S. For these 10 sites: lung, colon-rectum, breast, prostate, pancreas, leukemia, stomach, ovary, bladder, and liver-biliary, all but leukemia have been reported as being influenced by diet. Wynder and Gori (1977) have estimated that 40 percent of cancer in men and 60 percent in women are diet-related.

In your testimony you refer to cancer as a multi-stage disease and indicate that one of your cancer prevention goals is to interfere with the promotion stage through changes in our eating habits.

Question. Has the answer been found concerning the high-fiber low-fat diet?

Answer. The final most rigorous test to the current hypothesis that a low-fat, high-fiber diet can prevent colon cancer must come from conducting a large-scale clinical trial. The trial would address the issues of specificity not resolved in epidemiologic studies and uncertainty about clinical relevance of animal models. While the epidemiologic data which suggest this hypothesis is strong, confounding effects can only be controlled in an intervention trial. Because of the expense of conducting clinical trials, NCI is currently exploring the issues of appropriate biological markers and dietary compliance in small feasibility studies which upon successful completion would lead into a large-scale intervention trial.

CANCER SURVIVAL RATES

Question. NCI has received considerable criticism over the past year on its methods of determining cancer survival rates. For example, one criticism is that NCI's improved survival rates for lung cancer were due to earlier diagnosis and not longer life. How do you respond to these criticisms?

Answer. The survival rates published by NCI from the

Surveillance, Epidemiology, and End Results (SEER) program are relative survival rates and are unique in the world. Without them there would be little data for critics to use for their analysis. Their existence provides the opportunity to examine the effectiveness of prevention, diagnosis and treatment on a national basis. They are calculated by the life table or actuarial method. The relative survival rate adjusts for the normal mortality experience of a population group and is the probability of escaping death due to cancer. That is, if there were no causes of death other than cancer the five-year relative survival rate would give an indication of the proportion of cancer patients still alive five or more years after diagnosis. The life table method of determining the survival rate is a standard analytical method which allows us to use all available information in the computation of survival rates. With this method we are able to evaluate the survival experience of a group of cancer patients using all of the available data on each patient including those lost from follow-up to the time when their vital status was last known. These methodologies have been published and are considered by the scientific community to be acceptable methods of determining survival rates.

The lung cancer five-year relative survival rate based on the SEER program have shown small increases for patients diagnosed between 1973 and 1978, the latest year for which five-year survival rates are available. These survival rates have increased from 9.7 percent for patients diagnosed in 1973 to 11.6 percent by 1978 for white males. The comparable figures for white females are 15 percent for those diagnosed in 1973 and 17.6 percent for patients diagnosed in 1978.

By comparing the survival curves for lung cancer patients diagnosed in 1973 and 1978 and finding the time after diagnosis for patients diagnosed in 1973 that corresponds to the 1978 five-year survival rates (about three and a half years after diagnosis) we can estimate that in the extreme if all of the above increased were due to early diagnoses then the cases diagnosed in 1978 would have been diagnosed on the average about one and a half years earlier than were the 1973 cases. This is unlikely for several reasons: There is no nationwide large-scale screening program in place to enable us to diagnose lung cancer patients earlier in 1978 than in 1973. The survival curve for lung cancer patients becomes relatively flat at about three to four years after diagnosis which means that earlier diagnosis would affect the short-term survival rates, but not the long-term survival rates.

Our data are still showing increase in the survival rates seven and eight years after diagnosis, in fact the seven-year survival rate for white men increased by about 19 percent between 1973 and 1976. We can only conclude that the reported survival increases for lung cancer are real.

In summary we believe that the methods used to collect quality control and assess the nations cancer statistics are the highest quality. The data cannot be interpreted without other information on research progress, detection technologies and population changes. This information coupled with the statistics gives us perhaps the most complete picture of cancer of any country.

These statistics which help NCI guide and evaluate cancer progress are open to all to review and assess. We welcome such scrutiny.

FUNDING FOR OTHER PROGRAMS

Question. Dr. DeVita, I would like to ask you the same question just posed to Dr. Wyngaarden:

Given that Congress has stabilized the individual research grants at approximately the 6,000 level -- what other programs or mechanisms in your budget should receive more attention, and please explain why they are as or more important than grants?

Answer. All the other programs support basic research to a greater or lesser degree as research projects. One kind of center core grant provides direct research support to research project grants and over half of our intramural programs is pure basic research. Under epidemiology and prevention, basic research is supported by contract. The Institute has, and continues to support basic research as its highest priority. By far, research project grants have received the largest proportionate increase of all the funding mechanisms available to the Institute. I don't believe it's a question of whether one mechanism is more important than another but which mechanism is more appropriate to use for a particular scientific endeavor. For example, many aspects of AIDS research and drug development efforts are supported utilizing research and development contracts and intramural research.

As in the case of most scientific research endeavors, additional leads exist in the cancer field which can be exploited. Within the current total funds contained in the President's Budget we will support the highest-priority research efforts. With the biological explosion currently occurring and the state-of-the-art changing so rapidly, it is sometimes difficult to predict months in advance, the appropriate support mechanism to be used. Given the flexibility to rapidly adjust resources, the most high-priority efforts can and will be pursued in an effective and efficient manner.

CANCER PREVENTION

Question. I understand that prevention research is funded under the prevention and control line and not out of the research project line. Is that correct? Please explain.

Answer. Yes, in part. All 26 clinical trials are attempts to prevent cancer; many have basic elements to them and are supported by the cancer prevention and control budget. However, NCI prevention activities are funded both under the programs of Cancer Prevention and Control and the Cause and Prevention research thrust. A portion, about $170 million, of the support mechanism of research project grants is included within the Cause and Prevention thrust. Cancer Prevention and Control activities provide the impetus and are the foci for all NCI prevention activities.

Question. How much will the Women's Health Study cost in FY 1987?

Answer. Our estimate for the Women's Health Study cost is $5,721,000 in the FY 1987 budget.

Question. Will it cost more as time goes on?

Answer. The budget will increase during the next three years due to bringing in additional clinical units. In 1987 there will be an increase of 10 clinical units to a total of 13; in the following year there will be a total of 30 clinical units. During year six to ten, slightly less funding is required for the maintenance phase.

Question. I'm curious, do these prevention studies cost more at the outset or do they become more expensive as they progress? Why do they need to involve so many people?

Answer. Although there is an initial large investment at the outset of cancer prevention clinical trials associated with recruitment and accrual of study subjects, these types of trials continue to be expensive during their duration and more expensive in the later phases due to continued recruitment, drug procurement and data analysis.

Cancer prevention clinical trials need to involve a great number of subjects for several reasons: 1) the numbers must be sufficient so as to lead to statistically significant results considering the fact that even though these persons are at risk for cancer, the incidence is, nonetheless, low enough as to require large numbers to be enrolled; 2) participants are usually randomized to at least two groups, the treatment group and the placebo group; and 3) even though a person is enrolled, one may freely "drop out" of the study. To keep the number appropriate for statistical significance, a greater number of participants has to be enrolled to account for an estimated number who will "drop out".

For example, 30,000 women at high risk for breast cancer are required for a 10-year period in this trial. The sample size calculation for this study is based on the expected annual breast cancer incidence rates of women at high risk and the statistical power to detect an overall reduction.

The following cost estimates for the planned Women's Health Trial are indicative of the support required over the course of a well-designed prevention trial.

For 1986, $2.7 million is being directed to this effort. In 1987, approximately $6 million will be obligated for this effort -- for 13 clinical units. For the next three years about $14 million annually is projected to have the requisite 30 clinical units. For the balance of the trial -- six years -- approximately $10 million is needed annually for the maintenance phase.

Question. You say they cost more as the study progresses. Just so we have the big picture, what proportion of your prevention trials are in the early, less expensive years and what proportion are in the more expensive, later phase?

Answer. In the area of diet and cancer, there is currently only one large-scale macronutrient dietary clinical trial (Women's

Health Trial) which will be phasing in during FY 1987 and be at full-scale in FY 1988. Of the 26 clinical trials, there are 24 chemopreventive Phase III clinical trials involving micronutrients. In these ongoing clinical trials the diet is supplemented with natural or synthetic agents such as vitamins or minerals. Approximately eight to 33 percent of these trials are in the early, less expensive years and 16 or 66 percent are in the later phases. These are long-term trials and the length of these studies may be 10 or more years, so they continue to be expensive during the entire duration.

Question. In other words, you are going to need more money in prevention as the years go by?

Answer. Only through prospective, randomized, clinical trials, in which the dietary modification or the administration of a chemopreventive agent is the only variable, can the question of the benefit of dietary intervention in reducing cancer incidence among humans be resolved.

Epidemiologic and animal studies are much less expensive, but the former do not control for confounding effects, and relevance of results of animal to humans is always an issue. Clinical trials are expensive since the length of time of a study is long (10 or more years) and the frequency of occurrence of cancer in the general population is low. NCI is hoping to reduce these costs by using biological and chemical markers that would identify high-risk groups or serve as intermediate endpoints could shorten considerably the duration of studies and perhaps reduce cost by eliminating negative studies early in the evaluation period. While the procedures for conducting prevention risk clinical trials will improve with time, their utilization in attempting to answer questions of major public health significance will probably increase over the next few years necessitating increased funding requirements for these types of studies.

HTLV-I AND -II

Question. HTLV-I and -II are closely related to the AIDS virus and are known to cause leukemia in humans. Researchers have recently expressed concern that these viruses may be infecting the blood supply just as the AIDS virus has, and therefore may cause future cases of leukemia. What is your opinion on this situation, and how is NCI involved in finding a solution to this perceived problem?

Answer. HTLV-I and HTLV-II are only distantly related to HTLV-III. Although a causal relationship of HTLV-I and adult T-cell lymphoma (ATL) is reasonably well established, a link of HTLV-II to any human cancer is less clear. Based on spot testing, HTLV-I infection is quite rare or absent in most of the U.S., but pockets of infection do occur in the rural south eastern United States, where a maximum of about three percent antibody positivity has been found. Immigrant populations of Jamaicans or southern Japanese who have a higher HTLV-I exposure represent other possible antibody-positive individuals. This virus can be sexually transmitted and household transmission is reasonably certain. The incidence of ATL in the U.S. is quite low; estimates between 20 to 50 cases per year are reasonable. The reliability of currently

available blood antibody for research tests is still suboptimal. Currently, we do not anticipate a substantial increase in ATL cases because antibody-positive individuals in the U.S. are not generally blood donors. In the high-risk groups for HTLV-III, limited studies show that about 10 percent positivity for HTLV-I may be possible. However, these individuals should already self-exclude as donors.

Furthermore, the lifetime risk of an individual who becomes infected with HTLV-I to develop ATL is about one in one hundred, which is much lower than the potential of getting clinical AIDS after HTLV-III infection, which is at least one in three. Accordingly, from a scientific point of view, significantly increased transmission of HTLV-I incidence and increased incidence of ATL is not expected, and the present antibody tests are not accurate enough to warrant an approach similar to total screening of our blood supply.

TECHNOLOGY TRANSFER

Question. Approximately 15 percent of NCI's strategy on reducing cancer mortality by 50 percent by the year 2000 depends upon improving "technology transfer", specifically, encouraging U.S. hospitals to use state-of-the-art cancer treatments. How does NCI intend to improve technology transfer, and how will budgetary reductions affect these efforts?

Answer. Technology transfer efforts related to cancer detection and treatment include a number of programs and activities: NCI has developed a network of clinical cooperative groups, the Community Clinical Oncology Program (CCOPs), and the Cooperative Group Outreach Program (CGOPs). These programs make available the latest research results to practitioners through participation in clinical research to advance the state-of-the-art cancer treatment. The NCI also sponsors a major program to educate patients about their disease and their treatments, helping them to help themselves to get access to the best available care. The newest technology transfer effort is PDQ, the Physician Data Query system (a computer-based information system to provide physicians state-of-the-art information on cancer treatment that is accessible through the National Library of Medicine and through a number of commercial vendors.

NCI has estimated that 10 percent or more of cancer mortality could be reduced through the application of state-of-the-art treatment. The basic resources are now in place to narrow the gap between the state-of-the-art and treatments generally applied across the country. It is important to note that state-of-the-art treatment is not only aimed at reducing mortality, but improving quality of life in patients.

CHEMOTHERAPY

Question. Approximately 15 percent of NCI's strategy on reducing cancer mortality by 50 percent by the year 2000 depends upon improved treatment of micrometastases using chemotherapy. Chemotherapy has had relatively little success with common cancers and only seems to be effective against rare or unusual types of

cancer. What new forms of chemotherapy does NCI intend to develop, and how will budget reductions affect these decisions?

Answer. First, it is important to emphasize that the treatment of cancer with drugs has been remarkably successful in a number of common tumors which affect adults. Breast cancer, small cell lung cancer, ovarian cancer and soft tissue sarcomas, all of which respond to chemotherapy, are not rare tumors. For example, as recently concluded at an international meeting on breast cancer, the treatment of premenopausal women at high risk for breast cancer recurrence with chemotherapy can reduce mortality in this disease by 25 percent. Similar improvements have been shown for young adults with tissue cancers of the soft tissues (connective tissue, fat cells, and muscle) and tumors of bone (osteosarcoma).

Particularly striking treatment advances have been made for patients with lymphomas. Lymphomas, as a group occur 42,000 times a year in the United States and represent the sixth most common cause of cancer. This disease is frequently curable because of advances in chemotherapy.

Testicular cancer is uncommon - but not rare. This disease affects over 5,000 men in the United States each year, and is the most common cause of cancer in men between the ages of 18 and 35 years. In 1973, only five percent of men with metastatic testes cancer could be cured. Today, the cure rate is approaching 90 percent. This impressive cure rate is attributable to advances in clinical chemotherapy, and the discovery of new drugs particularly in the platinum derivatives.

During the past year, two highly effective forms of therapy have been identified for hairy cell leukemia, including recombinant interferon and the NCI-developed enzyme inhibitor, deoxycoformicin. The majority of cases of this fatal disease can now be controlled by either of these agents.

Consistent with the move towards increasingly rational selection of drugs useful in the treatment of cancer, the process of drug discovery has changed over the past decade. New sources of candidate compounds are being explored.

For example in 1984, the National Cancer Institute initiated a new type of grant to support national cooperative drug discovery groups. These groups are multi-institutional and multi-disciplinary, established for the purpose of bringing together the best scientists in drug synthesis, biochemistry, pharmacology and clinical trials to focus on the development of new compounds. These groups are now pursuing important new leads in the development of monoclonal antibodies, and inhibition of oncogene expression as specific cancer treatments. It is believed that this new, more broadly based effort will allow a concentration of all the talents needed to bring compounds from the stage of concept to clinical trial. Most recently, the National Cancer Institute, in collaboration with the National Institute of Allergy and Infectious Diseases has sought to establish National Cooperative Drug Discovery Groups for the design of new drugs useful in the treatment of AIDS.

In addition, new candidate anticancer drugs are now being screened in the NCI intramural program by testing against human tumor cells which can now be grown in tissue culture. It is expected that this method of selection will allow greater success in finding drugs with specific activity against human cancers. The NCI has begun by concentrating on screening new drugs against a large panel of human lung cancer cell lines. Lung cancer remains one of the most common, but least treatable tumors. It is also the only major cancer which is rapidly increasing in incidence. Since lung cancer cells have certain unique properties, it is expected that using these cells in culture to screen new drugs will discover compounds with selective toxicity to lung tumors. For example, some lung cancers activate foreign compounds, and knowing the mechanism underlying this process may help in the design of lung cancer-specific drugs.

Other approaches are now being undertaken to discover new leads in drug development. Compounds which are able to stop tumors from spreading (antimetastatic compounds) are rapidly approaching the point of clinical testing in man and other agents which mature cancer cells into normal cells (differentiating agents) such as hexamethyl bisacetamide have just begun clinical testing. These agents offer a completely new approach to eradicating cancer - rather than depending on cytotoxic cell kill, these drugs mature the cancer towards normalcy, or stop it from spreading to vital organs such as the brain, liver and lungs.

Drug resistance is an important problem in cancer medicine. Many patients after an initial excellent response to chemotherapy, will relapse with drug resistant tumor cells. The gene responsible for multiple drug resistance has been isolated during the past year. The unique protein which it encodes on the surface of resistant cells has been identified, and experiments are underway to develop this knowledge as an important target for new chemotherapeutic agents.

In addition, new compounds are being systematically isolated from the fungal, bacterial and plant worlds for the first time. Previous efforts in fermentation research, which have yielded a wealth of important antitumor drugs, have focused on only one family of microorganisms, the streptomyces. Natural product fermentation research is otherwise almost completely untouched. Preliminary work suggests that other fungi, plants, and bacteria may be an important source of unique new drugs.

Current plans are for a major re-emphasis of natural product drugs. Collection programs are planned in both the plant and marine animal areas which have not been examined for antitumor substances. Emphasis will also be placed on types of microorganisms, plants, and animals which are virtually untapped as sources of antitumor drugs, including fungi, algae and marine organisms.

The National Cancer Institute is prepared to take the lead in the plant, marine and more difficult microbial areas and to develop these as sources of new antitumor agents. These projects have tremendous potential for the discovery of truly novel anticancer agents.

At the same time extensive work continues on the interaction of cancer chemotherapeutic agents of established value. A highly favorable interaction between the folic acid vitamin, leucovorin, and 5-fluorouracil has been identified at the biochemical level, and improved results of this combination have been reported in patients with colon cancer and breast cancer, as compared to the results of 5-fluorouracil alone.

If the Institute's budget were substantially below the President's request, most of these programs would have to be postponed or curtailed.

TREATMENT AND PREVENTION RESEARCH

Question. The largest segment of your research budget, almost 40 percent, is devoted to cancer treatment research. Taking into account the facts that chemotherapy has had limited success in the treatment of cancer and that the precedent for successful disease control lies with prevention, what do you feel is the proper balance at NCI between treatment and prevention research?

Answer. Treatment research is more than chemotherapy. Taken together all treatment research has led to the cure of half of all serious cancers with bright prospects for further gains. While prevention is our primary goal we will always need effective treatment for those who are already destined to get cancer. Treatment research comprises about 40 percent of the research budget, if one considers it as a percent of the total NCI budget for 1987, treatment research comprises about 25 percent of the budget. That subset of treatment research devoted to chemotherapy is only about 10 percent of the total budget.

In 1987, we will spend about $321 million in cancer prevention research, or nearly 28 percent of our total budget. Our resources are distributed so that we can pursue those scientific leads which currently exist in both treatment and prevention. For example, if current research in either cancer prevention or treatment were to uncover a new avenue of approach, then we would move to redirect our resources into that area to take advantage of the new information.

ADJUVANT CHEMOTHERAPY

Question. Expectations were high in the early 1970s for adjuvant chemotherapy in the treatment of cancer. Adjuvant chemotherapy has proved to be effective only in certain forms of cancer, and even in these cases, sharp controversy has emerged over whether the gains are great enough to outweigh the side effects. What are your current thoughts on the controversies associated with adjuvant chemotherapy, and where will NCI be heading in the future on this issue?

Answer. Today, there is no controversy as to the essential correctness of the fundamental hypotheses of adjuvant chemotherapy. Indeed, the successful application of adjuvant chemotherapy in breast cancer and sarcoma is one of the outstanding accomplishments of the decade. Data, some of which are more than 20 years old, have demonstrated that adjuvant chemotherapy is effective for patients with pediatric, rectal, breast and sarcomatous cancers.

For example, the consensus conference on adjuvant therapy of breast cancer, held at the NIH in September of 1985, concluded that chemotherapy was the indicated therapy for premenopausal breast cancer patients with positive lymph nodes, while antiestrogen therapy is indicated for postmenopausal patients with positive lymph nodes. When combined with definitive radiation or surgery effective chemotherapy definitely results in more patients surviving free of their malignancy and a 25 percent reduction in mortality. Currently, challenges exist as to how adjuvant chemotherapy can be made more uniformly efficacious and less toxic. New approaches to reduce the side effects and increase clinical benefits are being intensively studied in testicular cancer, colon cancer, breast cancer, lung and melanoma cancer.

1) Testicular Cancer: Currently, the use of cis-platin + Velban + Bleomycin result in a 95 percent cure rate but is associated with substantial side effects. Research focusing on a substitute agent (VP-16 for Velban), less toxic analogues (CBDCA for cis-platin) and with two drug regimens (VP-16 + cis-platin) rather than three, promises to provide equivalent benefits with diminished toxicity.

2) Colon Cancer: Last year, we reported an important study in which adjuvant therapy improved survival for patients with colon cancer - one of the most common cancers with approximately 100,000 new cases in the United States each year. Ongoing clinical trials are evaluating combinations of chemotherapy and biologicals to improve the cure rate in this disease. This promising avenue of research is representative of the general effort to utilize chemotherapy and biological response modifiers together, capitalizing on basic research advances to improved cancer cure rates in man.

3) Breast Cancer: Attempting to build upon the positive benefits already achieved, studies of more intensive chemotherapy and combinations of drugs and hormones are ongoing. It is already clear that adjuvant therapy of breast cancer significantly improves patient survival and that this can be translated to improved mortality figures on a nationwide basis.

4) Lung and Melanoma Cancers: Last year we also reported a positive adjuvant chemotherapy study in a non-small-cell lung cancer which is undergoing confirmatory trials. This study is particularly important as lung cancer affects over 120,000 Americans each year and the incidence of the disease is nearly doubling each 15 years. Attempts to employ new monoclonal antibodies and LAK cell immune modulation are promising new efforts for the future.

The goal for adjuvant therapy today is to find effective adjuvant therapy for patients with the common adult malignancies which have proven resistant to therapy when they recur as metastatic tumors. The NCI plans to employ new types of agents and new strategies to achieve greater benefits at lesser morbidity.

Question. The Health Research Extension Act of 1985 established Associate Directors for Prevention in only three Institutes -- NCI, NHLBI and NICHD. Do you see these Institutes having a greater need to focus on prevention research?

Answer. The NCI has in place a strong focus on prevention. Two of its four research divisions focus chiefly on cancer cause and prevention. The Division of Cancer Etiology does the basic research in chemical carcinogenesis, viral oncology and epidemiology which aim to provide the knowledge for cancer prevention. The Division of Cancer Prevention and Control follows through with human cancer prevention trials and cancer control research, to assure widescale benefits to our population from the basic research. The Division of Cancer Prevention and Control has clinical studies and research programs in diet and cancer, chemoprevention, smoking prevention and cessation, and cancer detection.

RADON GAS IN D.C. HOMES

Question. One of Washington's TV stations recently ran a news series reporting on the dangers of radon gas in homes in the Washington area. Did you see this report, or are you familiar with this problem?

Answer. Measurements performed by a reporter in the Washington D.C. area indicated that 16 of the 40 homes tested, or 40 percent, had radon-daughter levels exceeding four picoCuries per liter, the EPA's so-called "action level" for remedial action. These figures were similar to those from another small survey in 1982 conducted in Damascus, Maryland. Measurements in homes in Pennsylvania built along the Reading Prong, a geological formation which contains uranium deposits, however, indicate that even higher levels of radon gas concentrations are possible in residential areas. In some houses much higher levels have been measured than the estimated average in the United States of approximately 0.4 to 0.8 picoCuries per liter (0.2 WLM per year).

Question. Can you tell us about this problem?

Answer. Unfortunately, there have been no comprehensive national surveys in the United States as a whole, or in any state, to accurately estimate the extent of this problem. The National Council on Radiation Protection has estimated that approximately 0.14 percent of the population might be exposed to greater than 0.2 WLM per year (four picoCuries per liter), assuming exposure distributions based upon surveys conducted in Canada, while other estimates are as high as one percent.

Question. How dangerous to health is radon gas?

Answer. The studies of underground miners exposed to high levels of radon gas and radon-daughter products (over 10,000 picoCuries per liter) have conclusively linked this exposure to increased rates of lung cancer. Investigations in Sweden have also hinted that the lower, but still elevated, levels found in some residences might also be hazardous. Complicating these investigations is the suggestion that cigarette smoking combined with radon gas exposures might be especially hazardous.

Extrapolations from high-dose miner data to lower-dose residential exposures have not been validated. However, they have been used to develop a wide range of estimates of the lung cancer risk in the United States possibly attributable to radon exposure. The National Council on Radiation Protection, for example, has estimated that 9,000 of the over 120,000 lung cancer deaths occurring each year in the United States might be attributable to radon levels in the home. A recent editorial in the New England Journal of Medicine concluded that one in five lung cancer deaths among non-smokers might be caused by residential radon levels. Scientists writing in Nature have estimated that radon gas might increase the natural lifetime risk of lung cancer, about four percent, by 0.12 percent in the United States population.

While levels of radon in dwellings and other buildings are generally quite low, especially in comparison with levels in uranium mines, statistically so many millions of people are exposed to these levels that the rate of lung cancer in the population as a whole may be affected, even though few families or individuals would be at particularly high risk.

Question. Do you have or are you planning to conduct any studies on the effects of high concentrations of radon gas in the home?

Answer. Epidemiologic studies on the risk of lung cancer possibly associated with radon exposures in the homes are now being conducted even though we are aware of the various limitations associated with such investigations. For example: 1) The radon levels in the home are much lower than in uranium mines, and it may be difficult to detect a small increase in lung cancer risk. 2) Other major risk factors for lung cancer, such as cigarette smoking, will have to be carefully evaluated to minimize spurious results. 3) The mobility of people in the United States and in other countries makes it difficult to obtain accurate lifetime exposure estimates to radon. This is particularly important since the latent period between exposure and the eventual development of lung cancer may be on the order of 10 to 20 years, and measurements made in the house of last residence may not be relevant to the exposures that were experienced during childhood and later life. 4) Homes have also been modified to be more energy efficient, and measurements made today may not be representative of conditions that existed 20 or 30 years ago. 5) While measurements can be made in residences, estimates still have to be made with regard to the amount of time a person actually spent in his residence. 6) Finally, radon levels vary from room to room and it may be difficult to obtain an average value for an individual.

Nonetheless, we think that radon levels in private dwellings represent a potentially serious public health problem, and we have initiated three new investigations in New Jersey, Sweden and China to evaluate whether these exposures are related to increased rates of lung cancer. Some of New Jersey municipalities are included in the Reading Prong, a geologic formation which contains uranium deposits. A recently completed case-control study of lung cancer among New Jersey women is being enhanced by placing radon detectors in long-term residences of approximately 800 persons who developed lung cancer and 800 controls. Two detectors will be placed in each home for approximately one year, and

exposure levels will be compared between the cases and the controls. This study is being conducted in collaboration with the New Jersey Department of Public Health.

Similarly, in Sweden, radon detectors are being placed in the homes of 200 women who developed lung cancer in Stockholm and 400 controls. Radon levels are high in Stockholm because of the use of alum concrete in buildings, having high radium content, and also because of the geologic area upon which the city is built. Another lung cancer case-control study has recently been initiated in Shenyang, China, to evaluate indoor and outdoor air pollution. As part of this investigation, radon detectors are being placed in the homes of 460 female lung cancer cases and a comparable number of controls. Preliminary results from these studies should be available in the next year.

Question. Are you requesting sufficient funding to explore this problem and, if not, how much will you need?

Answer. Our current strategy has been to add a radon component to on-going lung cancer case-control studies which were being conducted for other reasons, for example to determine the influence of involuntary smoking, indoor and outdoor air pollution, diet, and other factors associated with lung cancer. If the radon components for these studies indicate that additional large-scale studies are required in the United States or in other countries, we would then request support to explore this problem in much greater detail.

Question. Can you offer any suggestions to the residents of the D.C. area?

Answer. If levels are unusually high, it is possible to lower them by covering the basement walls with certain sealants, and by increasing the air exchange in the house. Maryland residents who want to have their homes checked for radon can call 301-225-6981, the State Health Department's special hotline with information on public agencies and private firms that perform radon tests.

The methods of reducing radon daughter levels are simple in concept, though perhaps not so simple to carry out: Reduce the influx of radon, increase house ventilation, and remove radon daughters by filtering out airborne dust. If home owners detect unusually high concentrations of radon indoors, they can seal cracks and openings in the basements with epoxy sealants, ventilate buildings with heat exchangers, and remove indoor airborne dust with high-quality air-cleaning systems. At present, however, the problem of radon needs further evaluation because it is unclear what should constitute an "unusually high" level.

Question Submitted by Senator William Proxmire

REDIRECTION OF RESOURCES

Question. I note from your justifications that you have changed some of your 1986 priorities over the last 12 months. For example, you planned to spend $111,265,000 in 1986 on research into

physical and chemical carcinogenesis last year but currently project spending at only $108,309,000. On the other hand last year's estimate of $133,092,000 for tumor biology has increased to $151,089,000. Can you tell us what caused this shift of priorities?

Answer. The estimates of spending among the 10 research programs are based on historical patterns of grant and contract applications and the funding which can be provided to these applications based on the President's Budget request. Since the development of the 1986 Congressional Justification, the distribution of applications among the 10 programs shifted from what we expected. Thus funding of physical and chemical research is now estimated at $108 million in 1986. In addition, Congressional action increased the total Institute budget by $132 million allowing additional funding in many important research areas such as tumor biology. The FY 1986 funding for tumor biology is now estimated at $154.4 million.

Question Submitted by Senator Quentin N. Burdick

COMMUNITY CLINICAL ONCOLOGY PROGRAM

Question. The Community Clinical Oncology Program has contributed to the NCI's successes by establishing a research framework throughout the country. I am especially pleased to note that in my part of the country, the costs per patient for treatment, and for the corresponding production of essential research data, are significantly lower than are the comparable costs of conducting research at other sites. I believe the CCOP cancer centers are key to continuing cancer care and research, and to the overall goals of the NCI. What steps will the NCI take to ensure the viability of this program and the continued diffusion of the cancer center network?

Answer. NCI staff is currently developing a Request for Applications (RFA) for the Community Clinical Oncology Program to provide continuing opportunities for participation by community physicians in clinical and cancer control research. The existing CCOPs now participate in clinical trials through affiliations with NCI-funded cancer centers and clinical cooperative groups. While it is our belief that the CCOP is an important vehicle to the NCI to ensure the most comprehensive state-of-the-art treatment to cancer patients throughout the nation, an ongoing evaluation program is underway to evaluate the effect of this program in all of its objectives.

Questions Submitted by Senator Frank R. Lautenberg

CANCER PREVENTION AND CONTROL PROGRAMS

Question. The NCI strategy of cancer control is grounded in the concept that cancer development occurs in an initiation and a promotion stage, and emphasizes the role of prevention, detection and treatment. The FY 1987 appropriation estimates for the Cancer Prevention and Control Programs indicate decreases in both the Cancer Prevention and the Community Oncology Programs. Since the

Programs are small, these decreases will have devastating impacts on the recipient state hospitals. Given the two-stage model of the cancer development strategy and the emphasis on prevention, detection and treatment, how can these decreases be justified?

Answer. Before cancer control interventions can be recommended to the public, sound, scientifically-based evidence should be amassed to assure that the expected benefits from the intervention are justified in comparison with the costs of achieving the intervention. This strategy underlies the cancer control research program logic and has been used to identify and evaluate those research projects to target for funding reductions. When reductions are necessary, they should be effected only through a careful review of all research programs for the assessment of potential benefit to be derived from each project, as well as a reassessment of the degree to which non-Federal resources can be applied to achieve the same benefits.

We are reassessing the research opportunities to ensure that expected public health benefits are maximized. Any decrease in resources levels could result in a delayed momentum however all efforts are being coordinated to continue the support of the highest priority efforts. One program that has been reduced considerably is the Centers of Radiological Physics. The Centers have conducted quality control research on radiological facilities around the country, specifically for the standardization of radiation facilities used in clinical trials -- but also yielding benefits to non-clinical trial patients treated in those facilities. Originally these centers were supported by Federal funds with the intention and expectation that the activity would eventually be supported by the local communities possibly on a fee-for-service basis. The timetable for transferring the responsibility for supporting these centers from the Federal government to the private sector now has been accelerated.

This reduction is in contrast, for example, to the area of chemoprevention. We are making every effort to maintain chemoprevention research at near optimum levels because of its potential to lead to major reductions in cancer in the future.

Question. Which projects in the Cancer Prevention and Community Oncology Programs will be eliminated and diminished?

Answer. In the areas of Cancer Prevention and the Community Oncology program, the FY 1987 budget will require that only the most promising research can be supported, and consequently that some other programs must be diminished. The Centers for Radiological Physics Center previously mentioned are being phased out in FY 1986 to increase funds available for other programs. The Centers have been supported by NCI since 1974. NCI has always intended to phase-out support for these centers when communities could assume the responsibility for quality assurance in diagnostic and therapeutic radiation facilities. The FY 1987 budget for the Community Clinical Oncology Program will entail a reduction from current levels of support. The program will continue to provide service to communities across the nation, but at a diminished level compared to prior years.

Question. One of the long-term goals of the NCI is to

decrease the incidence of cancer in the U.S. by 50 percent by the year 2000. What programs and initiative have or are being developed to reach those states with no or limited cancer centers?

Answer. In 1985, the NCI established guidelines for support grants for consortium cancer centers. Such centers would bring together institutions and agencies within communities or regions into a consortium organization to facilitate cancer prevention and control control research. This program could be utilized by groups within states with no or limited cancer centers. In addition, a number of academic institutions are attempting to develop new single institution-based centers. Several of these are located in these states and it is expected that some will compete successfully for support.

A major new initiative entitled "Technical Development in Health Agencies" was announced last fall for funding in late FY 1986. This initiative provides funding for public health departments to improve their technical capabilities to engage in cancer prevention and control activities consistent with NCI's year 2000 goal. We are pleased that 25 State Health Departments and four local jurisdictions submitted applications for this program. These applications are under review and we expect to make between five and 10 awards in the current fiscal year. Depending on the availability of funds in the future, we plan to initiate additional capacity-building programs in accordance with NCI's scientific and technical expertise in cancer and the commitment of State and local governments to support service programs for their own constituents.

Question. What is the likelihood of the development of a cancer center in New Jersey in the near future?

Answer. We have been encouraged by the interest of several groups in New Jersey in developing a cancer center. One group is actively pursuing the possibility of a statewide consortium. There is also increased activity in the medical academic community directed towards development of additional cancer research and a cancer center organization. As is true for any NCI-funded cancer center, however, the proposed plan of research for any new center, require standard peer-review evaluation by the appropriate NIH/NCI study section.

Question. What other specific cancer research programs are anticipated for New Jersey in the near future?

Answer. New Jersey is one of 25 states and four other local jurisdictions that has applied for a grant entitled "Technical Development in Health Agencies" to assist health departments in developing their technical capabilities to engage in cancer prevention and control programs. We expect to make between five and 10 awards under this program by late FY 1986.

In addition, New Jersey is now part of the Surveillance, Epidemiology and End Results (SEER) program and thus has a population-based cancer registry. New Jersey, therefore, is in an excellent position to submit grant applications for research in cancer prevention and control. NCI's Division of Cancer Prevention and Control strongly encourages the development of grant applications relating to cancer prevention (e.g., smoking,

nutrition, occupation), cancer detection (e.g., cervical and breast cancer), and improved cancer treatment systems in the community. Unsolicited applications are encouraged to be submitted for review and possible funding under the general grant pool of NCI. Additionally, NCI is interested in program-project grant applications for the Cancer Control Science Program. This program allows multiple intervention research studies to be funded along with appropriate core support for shared resources (e.g., biostatistics) under a single grant. Announcements of the availability of this mechanism have been made several times in the past and will be repeated this year.

Question. An important aspect of the NCI mandate is to develop the means and methods to apply the best cancer treatment protocols in health care practice. Yet, the Community Clinical Oncology Programs and the Cooperative Groups Outreach Programs, which are major Community Oncology Research Programs, have been proposed for cuts in the FY 1987 Appropriations. What was the justification for decreasing the proposal for Community Oncology Research Programs for FY 1987?

Answer. The funding proposed for the Community Oncology Research program reflects a decrease over prior year funding levels, because of the overall constraints of the budget and the number of high-priority prevention programs available for funding in FY 1987. The distribution of funds to all these programs reflects the NCI's judgment of which programs will contribute significantly to the reduction of cancer mortality and at what reduced levels these programs can continue to be viable and to contribute to decreases in mortality.

Question. What substitute or alternative programs will be provided to ensure that communities will continue to have access to the latest and best cancer treatment?

Answer. A number of programs are available nationwide to ensure that communities will continue to have access to the most current cancer treatment. Education programs through a number of professional groups, such as the American Society of Clinical Oncology, the Oncology Nursing Society, etc., should stimulate community involvement in cancer control treatment efforts to reduce cancer mortality. The Institute's national Cancer Information Service (CIS) continues to provide information on sources of cancer treatment through its 20 regional offices and the national back-up office. Each of these offices is linked directly through a computer terminal to the PDQ database for rapid and timely response to treatment related questions from the public and health professionals.

CIS offices respond to 400,000 inquiries yearly. In 1985, 15.6 percent of all inquiries were questions related to cancer treatment. In fact, 4.6 percent of callers asked about clinical trials. CIS offices referred 27,626 people to NCI-sponsored clinical research programs in 1985. The PDQ database is used extensively by CIS staff members to respond to these inquiries.

Question. To accomplish the mission of the Cancer Prevention and Control Program, the NCI developed a five Phase intervention program which requires close cooperation between the

research and development activities of the nation's pharmaceutical industry. What Phase I prevention and control research projects are currently in operation in New Jersey?

Answer. Although currently there aren't any Phase I prevention and control research projects in operation in New Jersey, there are a number of ongoing cancer prevention and control efforts in the state. New Jersey is now a part of the Surveillance Epidemiology and End Result (SEER) program and thus has a population-based cancer registry that could be used as a resource for grant proposals concerning the specific cancers with high incidence in New Jersey. The state also has 16 institutions which are part of the Community Clinical Oncology Program.

Question. Which pharmaceutical companies in New Jersey are involved in Phase I cancer research projects in New Jersey and in other states?

Answer. Two New Jersey pharmaceutical companies are currently involved in Phase I projects: McNeil Consumer Products Company of New Brunswick and Hoffman-LaRoche of Nutley. The projects they support are conducted outside the state of New Jersey.

Question. If there are no Phase I cancer research projects currently in operation in New Jersey, what are the reasons for this omission?

Answer. No applicants from New Jersey submitted proposals to be funded in Phase I projects. Project needs were advertised in the NIH Guide and Commerce and Business procurement documents published by the Department of Commerce.

Question. What efforts are being made to develop the expertise in New Jersey and in other heavily populated states to afford the opportunity to conduct Phase I research projects?

Answer. All locales are encouraged to submit applications to the NIH, as either unsolicited proposals or in response to specific Institute initiated announcements. After an application is reviewed and approved by chartered review committee, decisions are then made regarding the support of specific projects. This is done not only for the NCI but indeed for each component of NIH.

As previously mentioned, New Jersey is now a part of a SEER population-based registry. It is also one of the states that has applied for a grant to assist the health departments to develop their capabilities in cancer prevention and control.

Question. The Phase II and III clinical trials provide cancer patients with the state-of-the-art treatment. What Phase II and III clinical trials programs are currently in operation in New Jersey?

Answer. The purpose of a Phase II study in cancer therapy is to determine efficacy of a new treatment. Once a tolerable dose is established in Phase I trials, the treatment is tried in patients with specific diseases in Phase II studies. Only a small number of patients are placed on these trials. If there is no

response, the studies are closed. If the treatment appears to have an effect, then the treatment is moved into Phase III, in which the new therapy is subjected to comparisons with established treatment. If, for example, patients with breast cancer were found to respond to a new treatment, that treatment would be compared to a standard treatment such as adriamycin. Phase III studies accrue a larger number of patients and are conducted in several institutions simultaneously.

Most Phase II/III studies supported by the National Cancer Institute are conducted by the Clinical Cooperative Groups. These organizations design the protocols to test new treatments, accrue patients to the studies, and analyze and publish the results. Because of the size of NCI's clinical trials organization, hundreds of protocols and thousands of investigators are involved at any point in time. Physicians throughout New Jersey have access to these trials for their patients either at New Jersey institutions or at major cancer centers in New Jersey and Philadelphia. Because of the changing mix of protocols and each protocol's eligibility requirements, it has been difficult in the past for community physicians to know where an appropriate research protocol might be available for a particular patient. That is why the NCI designed and made available the PDQ system. This computerized database allows physicians to find out whether the NCI has an open research protocol in any specific disease, to determine whether the patient is eligible for the experimental treatment, and to find the nearest location where the patient can be treated on that protocol.

In the area of cancer prevention and control, the community clinical trials programs in New Jersey include 19 hospitals that participate in the Cooperative Group Outreach Program and 12 hospitals affiliated with four Clinical Community Oncology Programs.

There are no chemoprevention Phase II and II clinical trials in New Jersey at this time. However, there are several in New York City which are open to New Jersey residents.

Question. How are these programs being developed and improved?

Answer. The NCI encourages the submission of research applications. It is through this process that the majority of cancer research is funded. In addition, if the Institute, with the sanction of its outside scientific advisory bodies, determines that an initiative such as the Clinical Community Oncology Program (CCOP) should be implemented, a request for applications will be initiated. In the case of the community programs, physicians who may be affiliated with a CCOP participate in clinical trials through an NCI-funded clinical cooperative group and/or cancer center. The cooperative agreement funding mechanism allows for significant interaction by the community organization with NCI staff for exchange of information and advice. However, the individual programs are organized and managed by the community participants.

The clinical cooperative groups are largely responsible for developing and improving their own protocols, with oversight from NCI on issues of safety and duplication of effort. However, the

NCI has provided initiatives for setting up a number of intergroup trials in prostate cancer (treatment with hormonal agents), head and neck cancer (treatment with preoperative chemotherapy), malignant melanoma (reduced size of surgical excision), and bone marrow transplantation with high-dose chemotherapy for breast cancer. The NCI is currently providing an increased measure of coordination for the cooperative groups so that their protocols can be completed more quickly. In large clinical studies it has been difficult in some cases to complete accrual in an optimum timeframe without such intergroup participation.

The chemoprevention initiative is a very high priority of the Institute, as indicated by the CCOP effort. Specific projects in chemoprevention are developed locally by interested parties in response to such NCI requests for applications. Projects are reviewed by scientific peer review and evaluation is undertaken during the course of the activity.

Question. What is needed to increase the number of Phase II and III projects in New Jersey?

Answer. In order to increase the number of Phase II and III projects in New Jersey (or any state) additional investigators need to submit applications for such projects, either unsolicited or in response to an NCI initiative. Actual funding depends on the quality of the project as indicated by peer-review priority score.

In addition, as noted above, the physicians and patients in New Jersey have access to a wide variety of protocols through the Cooperative Groups. Patients eligible for protocol treatment can be referred to a large number of institutions in or near the state. The complete list for each protocol is available in the PDQ system.

Question. What is needed to update these programs to include Phase I projects?

Answer. In cancer treatment, clinical trials for new drugs, biologics and some radiation treatments begin with a Phase I study. This is a test in a very small number of patients to determine the maximum dose of the new treatment that can be tolerated. These few patients are the first humans to receive the new agent or treatment and must be closely monitored by experienced teams of investigators. Because these trials are conducted in patients who have life-threatening disease and the effect of the treatment is unknown, the institution must have specialized facilities to deal with any unforeseen serious toxicities. Phase I studies often include numerous tests on the patient to determine the pharmacokinetics of the new agent. All of this -- the specialized training and experience of the investigative team, the extensive support facilities, and the complex laboratory tests -- limit the number of institutions in the United States capable of performing Phase I studies in cancer patients. At this time, the National Cancer Institute contracts with eight institutions for drug studies and 11 institutes have done Phase I studies of biological response modifiers under contract. None of these contractors are in New Jersey. At this time it would not be scientifically sound to combine Phase I studies with Phase II and Phase III trials in the cooperative groups.

In the area of prevention, however, New Jersey investigators have the same opportunity as those in other states to apply to participate in Phase I trials. Actual funding will depend on the peer-review group's priority score for the proposal.

Question. Pediatric oncology research programs present special problems for the patient, physician, parents, and community. What is the proposed FY 1987 level of funding devoted to pediatric oncology research programs?

Answer. The proposed FY 1987 budget for pediatric oncology research is projected to be $18.9 million of which $10.8 million is supported through clinical cooperative groups.

Question. Which states are included in the pediatric oncology research programs?

Answer. Forty-one states and the District of Columbia are actively and directly participating in this research effort. The most densely populated states (such as New Jersey) are all currently involved. Of the nine states not participating (Alaska, Delaware, Idaho, Kentucky, Maine, Montana, Nevada, New Hampshire, and Wyoming), only one (Alaska), is not located contiguously with a state which is participating in NCI-sponsored pediatric oncological research. For example, a total of 74 active protocols are available to New Jersey pediatric patients. The entire spectrum of leukemias, lymphomas, sarcomas, brain tumors and other tumors are covered. Participating physicians are found throughout the state (including Summit, Hackensack, Trenton, Newark, etc.). A list of these physicians and protocols can be accessed through the PDQ system.

Question. What projects are being developed to include the heavily populated states, such as New Jersey, in the pediatric oncology research programs?

Answer. The National Cancer Institute uses a variety of mechanisms to support and promote pediatric oncology research efforts in the United States. This includes the Clinical Cooperative Group Program, Program Project Grants, Individual Investigator Grants (R01s), and Community Outreach Programs. The Cooperative Group Clinical Trials program in pediatrics are principally conducted by the Children's Cancer Study Group (CCSG) and the Pediatric Oncology Group (POG), each of which is a multi-institutional organization of Pediatric Oncology Hospitals, included in NCI's Cooperative Groups (along with specialized Wilms' Tumor Study Group and the Intergroup Rabdomyosarcoma studies). The overall Cooperative Group budget for 1987 is $49 million, of which approximately $10 million or approximately 20 percent is dedicated to pediatric oncology research. Clinical trials are conducted through the Cooperative Groups to evaluate new treatment regimens for benefit to children with cancer, and through the Community Outreach Programs, which disseminates these practices through the United States. Pediatric institutions seek membership in these Cooperative Groups and are evaluated by peer review; if found meritorious, they are recommended for funding through the Cooperative Group program. At present, most states are included in this program.

Question. If the proposed FY 1987 level of funding does not provide for the inclusion of all the states in the Pediatric Oncology Research programs, what amount of funding would be require?

Answer. Increased funding would not necessarily increase the number of states included, as this is determined by merit (scientific skill and resources), not geography. Similarly, Program Project Grants, which are large research projects located at individual cancer hospitals, are recommended for funding on the basis of merit, and an increased budget would not necessarily lead to wider geographic spread.

Question. Which programs and projects should be developed to bring all states with sizeable populations into the Pediatric Oncology Research program?

Answer. It is estimated that 7,000 children are diagnosed with cancer yearly. Of these, the two pediatric Clinical Cooperative Groups (CCSG and POG) register 4,000 patients, or 57 percent, as compared to a far smaller proportion of newly diagnosed cancer patients in adult Cooperative Groups. This suggests that the current budget levels for pediatric oncology research provide a relatively efficient support mechanism for this endeavor.

Question. Part of the success of the NCI cancer programs depends on the flow of the latest information from the basic research sector to the clinical treatment sector. How has the high-population density of New Jersey been used in the past as a research tool in the development of research protocols for studying this flow of cancer-related information?

Answer. New Jersey's population density as such has not specifically been used in developing such research protocols. Information collected in New Jersey is analyzed in a number of different ways to enhance the transfer and application of cancer research advances:

- The state of New Jersey became a participant in the SEER program in 1979. The SEER program routinely monitors cancer incidence and survival for temporal trends as well as differences between segments of the population. New Jersey has a total population in excess of seven million persons including one million blacks and half a million persons of hispanic origin. This racial mix, along with a varied industrial environment, makes the state a valuable addition to the NCI's cancer surveillance programs for research on the causes of cancer as well as the effectiveness of prevention and control efforts.

- The Community Clinical Oncology Program (CCOP) has four participating groups in New Jersey. One of the objectives of this program is to study the effectiveness of community diffusion of state-of-the-science treatment as developed through clinical trials research.

- NCI is developing and evaluating communications systems

to enhance the flow of the latest research information. One such program is the Physician Data Query System (PDQ), which is aimed at informing medical providers. Another is the Cancer Communications System, which provides information to the general public. New Jersey is served by both of these systems.

Question. How will New Jersey's dense population be factored in for future research to improve the outreach programs of the NCI?

Answer. New Jersey researchers and health officials are now in an excellent position to apply for funding, contingent upon the usual considerations for peer review and funding availability, for investigator-initiated grants related to cancer prevention and control in general and specifically for Cancer Control Science Program grants. Because of its relatively high cancer rates, population density, racial-ethnic characteristics and linkage to the SEER program, grant applications that take advantage of these factors and are judged to be sound scientifically, or have a good opportunity to be funded, subject to the availability of funds. The New Jersey State Health Department's application for a "Technical Development in Health Agencies" grant is an example of the State's interest in NCI activities that builds upon these factors.

Question. How will the Community Clinical Oncology programs in New Jersey be improved in the future?

Answer. All the CCOPs will be encouraged to participate in cancer control research and to increase accrual to clinical trials. Individual CCOPs can initiate local expansion and improvement by adding physicians, hospitals or research bases to their programs if approved by NCI program staff. Further, as a result of the nationwide evaluation of the CCOP, all of the CCOPs will receive the comments and suggestions for improvement that results from the formal evaluation.

National Institute of Allergy and Infectious Diseases

STATEMENT OF ANTHONY S. FAUCI, M.D., DIRECTOR

ACCOMPANIED BY:

JAMES B. WYNGAARDEN, M.D., DIRECTOR, NATIONAL INSTITUTES OF HEALTH

YVONNE H. du BUY, BUDGET OFFICER

PREPARED STATEMENT

Senator Weicker. Dr. Fauci, it is nice to have you. Please introduce your colleague, and why don't you go ahead. Your statement in its entirety will be placed in the record, proceed any way you care.

[The statement follows:]

STATEMENT OF ANTHONY S. FAUCI

Over the years, research conducted and supported by the National Institute of Allergy and Infectious Diseases (NIAID) has made major contributions toward improving the health of our Nation and the world. More than half a billion people around the world suffer from diseases that are under intensive study by scientists supported by the NIAID. The backbone of our efforts lies in research at the basic cellular and molecular biological level. Indeed, it is basic scientific research in immunology, immunologic and infectious diseases that has laid the groundwork for the extraordinary development of knowledge about the acquired immunodeficiency syndrome (AIDS). Because of the public health crisis brought about by AIDS, we have been reminded in a most emphatic way that fundamental research allows us to respond quickly and with considerable expertise to emerging health problems.

The need for basic research holds true for other diseases as well, diseases that perhaps have attracted somewhat less attention than AIDS over the last year, but that cause illness and death for millions of people. Pertussis, or whooping cough, for example, is a disease that affects children in a most dramatic way, but due to successful childhood vaccination programs is one not often seen in this country. When I was before this Committee a year ago, we discussed the problems regarding the pertussis vaccine and our efforts to develop a purified vaccine without the toxic side effects that have been the cause of great concern. I am pleased to report to you today a new finding that will enable us to move more quickly toward the development of a safe and effective vaccine. Scientists in our intramural program have cloned and sequenced two of the five genes in the pertussis organism that are linked to production of the toxin causing the devastating effects of whooping cough.

As I described for you last year with regard to the malaria vaccine, the cloning and sequencing of genes that code for the proteins of pathogenic organisms are extremely important in the development of genetically engineered vaccines, comprised of purified products that induce protective immunity in the absence of toxic side effects. In addition, a number of acellular candidate pertussis vaccines, made by extracting appropriate antigens from the whole cell, are being developed and tested with NIAID

support. This testing includes a large-scale efficacy trial in Sweden, where pertussis is epidemic and vaccination rates are low.

Although we have been successful in developing vaccines against a variety of microorganisms, particularly viruses, viruses as a group have long presented an obstacle to the clinician because they do not respond to the tools in our traditional armamentarium of pharmacologic therapies. The development of new antiviral agents gives us great hope for the treatment of the many serious illnesses caused by viruses, including AIDS.

One such drug is acyclovir, which, as I reported last year, is effective against a number of herpesviruses. It has been licensed for use in treating genital herpes. In studies recently completed, acyclovir was also demonstrated to be effective in treating herpes encephalitis and is undergoing testing for use in herpes zoster, or shingles. There is now evidence to suggest that acyclovir can prevent the devastating effects of neonatal herpes in newborn babies if given shortly after birth. Based on this promising evidence, clinical studies are proposed for 1987.

Antivirals have come under increasing scrutiny over the past several years due to our search for effective therapies for AIDS and the opportunistic infections that accompany it. Since my appearance before the Committee last year, the number of Americans known to be afflicted with AIDS has doubled. The 5-year projected mortality for persons with full-blown AIDS still approaches 100 percent. We estimate that more than one million Americans have already been infected with the virus and that approximately 10 percent of these will develop clinical AIDS within a 3-year period. With the identification of the causative virus, the delineation of the specific immune defect in AIDS, and the development of a blood test to protect the Nation's blood supply, we have now focused a great deal of attention on developing effective therapies for AIDS.

We have made great strides in developing and testing a variety of treatment strategies for both the underlying immune deficiency and for the array of devastating illnesses that actually cause the death of persons with AIDS. Phase I testing, which means determining the safest dosage and mode of administration, has been carried out for a number of antiviral agents, but it

is still too early to tell if the drugs being tested will prove to be of clinical value.

One area in particular that we are vigorously pursuing is immune reconstitution. Once we have in hand a drug that can kill or inactivate the AIDS virus, we must be able to restore the ability of the immune system to function in order to defend the body against the opportunistic infections and cancers that prove so deadly to persons with AIDS. The reverse is true as well: if we are able to bolster the immune system, it will be of only temporary help as long as the virus continues to reproduce and invade other cells. Therefore, we have developed a strategy of using a combination of antiviral therapy and immune reconstitution. During the past year, we have studied three sets of identical twins, one of whom in each set has AIDS. The three healthy brothers have donated bone marrow and lymphocytes to their twins with AIDS. An antiviral agent, suramin, was administered to the AIDS patients to suppress or perhaps eliminate the virus. It is still too early to report results from these studies.

Another way to boost the immune system is through the use of interleukin-2 (IL-2), a protein naturally produced by normal T cells. Over the past two years, we have treated several patients with IL-2 and found that it can result in a partial reconstitution of the depleted lymphocyte count and a minor reduction in Kaposi's sarcoma tumors, indicating that it may play a potentially important role in immune reconstitution therapy.

The NIAID is collaborating with the National Cancer Institute in a comprehensive program for developing and evaluating treatments for AIDS, AIDS-Related Complex (ARC), and opportunistic infections. This program will encompass "Drug Discovery Groups" to discover and create candidate drugs for testing, the evaluation of potential drugs in the test tube, and the establishment of AIDS Treatment Evaluation Units for clinical testing of experimental therapies.

Development of an effective vaccine against the AIDS virus is, of course, of the greatest urgency. Studies at the molecular level have shown that viral isolates obtained from different geographic areas of the world differ substantially in the envelope glycoproteins, that is, the carbohydrate-protein compounds that are found on the outer coating of the

virus. This variability will in all likelihood complicate our efforts to develop a protective vaccine. In addition, we need to know what constitutes protection in the case of HTLV-III/LAV. NIAID scientists have delineated the nature of the cellular and humoral immune response against the AIDS virus. These studies are critical components of the ongoing vaccine development strategy.

The NIAID is supporting natural history studies aimed at understanding how the disease is spread, and how it affects people in the high-risk groups over time. These studies may enable us to better understand such questions as what role various cofactors play in the development of disease in individuals infected with HTLV-III/LAV. We will also be expanding our international studies beyond Zaire in Central Africa to include populations in other areas of Africa, the Caribbean, and Asia.

AIDS is not going to disappear in the foreseeable future, and it is already a disease of monumental social and economic implications. The likelihood of future spread heterosexually into the general population will markedly compound the problem.

Thus, we are in the process of establishing an AIDS extramural management program to improve our planning and coordination of extramural research activities and to provide a central focus for our AIDS activities. This program will encompass all the things I have spoken of--therapeutics, vaccine development, clinical trials, pathogenesis, and epidemiology and international studies.

Tropical medicine and international health remain high priorities for NIAID. One of the many benefits from research in tropical medicine has been the application of drugs such as suramin, which were originally used to treat tropical diseases, in treating AIDS and the opportunistic infections resulting from AIDS. African sleeping sickness, or trypanosomiasis, is a tropical disease caused by a parasite transmitted through the bite of the tsetse fly. Suramin has been used effectively to treat the disease before it affects the brain. Once the parasite has invaded the brain, however, suramin is not effective. Preliminary studies in Africa have shown that a drug called difluoremthylornithine (DFMO) when used in combination with suramin can cure virtually 100 percent of patients who have chronic central nervous

system trypanosome infection. Even more recent work with a new form of DFMO has demonstrated that it results in lower toxicity than DFMO itself with equally promising results.

The study of immunology at the very basic level continues to provide insights and pathways to clinical advances in organ transplantation, autoimmune diseases, hypersensitivity diseases such as asthma, congenital immunodeficiency diseases, as well as the promising area of immunotherapy for immune-mediated diseases and cancer with agents such as interleukin-2 and the interferons.

This has been an exciting year for NIAID in approaching and crossing the threshold between basic scientific discoveries and the application of these discoveries to the control of a wide range of diseases within the mission of NIAID. This coming year will provide the opportunity to make further advances in the basic sciences of immunology and infectious diseases as well as to witness the fruition of the endeavors of previous years.

Mr. Chairman, the 1987 budget request for this Institute is $330,551,000. I will be happy to answer any questions.

BIOGRAPHY OF ANTHONY S. FAUCI

December 24, 1940. Brooklyn, New York

Education:

College of the Holy Cross, 1962 - A.B.; Cornell University Medical College, 1966 - M.D.

Professional History:

1966-1967, Intern, Department of Medicine, New York Hospital - Cornell Medical Center. 1967-1968, Assistant Resident, Department of Medicine, New York Hospital - Cornell Medical Center. 1968-1970, Clinical Associate, Laboratory of Clinical Investigation, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Bethesda, Maryland. 1970-1971, Senior Staff Fellow, Laboratory of Clinical Investigation, NIAID, NIH, Bethesda, Maryland. 1971-1972, Chief Resident, Department of Medicine, New York Hospital - Cornell Medical Center; Instructor in Medicine, Cornell Medical College. 1972-1974, Senior Investigator, Laboratory Clinical Investigation, NIAID, NIH, Bethesda, Maryland. 1972-present, Consultant in Infectious Diseases, The National Naval Medical Center, Bethesda, Maryland. 1974-1980, Head, Clinical Physiology Section, Laboratory of Clinical Investigation, NIAID, NIH, Bethesda, Maryland. 1977-1984, Deputy Clinical Director, NIAID, NIH, Bethesda, Maryland. 1980-present, Chief, Laboratory of Immunoregulation, NIAID, NIH, Bethesda, Maryland. 1984-present, Clinical Professor, Department of Medicine, Division of

Rheumatology, Immunology, and Allergy, Georgetown University School of Medicine, Washington, D.C., 1984-present, Director, NIAID, NIH, Bethesda, Maryland.

Board Certification and Military Service:

American Board of Internal Medicine - June 21, 1972. American Board of Allergy and Immunology - March 1, 1974. American Board of Infectious Diseases - October 15, 1974. U.S. Public Health Service, July 1968-June 1970; July 1972-present.

Professional Organizations:

American Federation for Clinical Research, American Association for the Advancement of Science, American Association of Immunologists, American Medical Association, Fellow, of The American Academy of Allergy, Infectious Diseases Society of America, American Society for Clinical Investigation, Fellow of the The American College of Physicians, Association of American Physicians, Collegium Internationale Allergologicum.

Offices Held:

Councillor, Eastern Section, American Federation for Clinical Research (AFCR), 1977. National Councillor, AFCR, 1978-1979. President, AFCR, 1980-1981.

Advisory Boards and Committees:

Chairman, Allergy and Immunology Committee, MKSAP V, American College of Physicians. Advisory Panel, The American Board of Medical Laboratory Immunology. Member, Committee on Clinical Immunology and Immunopathology, American Association of Immunologists, 1980-1985. Representative of American Association of Immunologists to the Examinations Committee of the American Board of Allergy and Immunology, 1981-present. Postgraduate Education Committee, American Academy of Allergy, 1979-1982. Member, NIAID Study Group on Immunology, 1980. Member, Section on Physiology in Clinical Science of the American Physiological Society, 1980-1984. Member, Subcommittee on the Classification of Vasculitis, American Rheumatism Association, 1980-present. Sub-committee on Clinical Sciences, Publications Committee, American Physiological Society, 1980-1984. Program Chairman, Group for AIDS, 1982-present. Member, American Federation for Clinical Board of Directors, American Board of Allergy and Immunology, 1984-present. Participant in the USA - People's Republic of China Immunology Immunology Cooperative Agreement, August 10-22, 1983, Beijing and Shanghai, PRC. Member, Scientific Advisory Board, Medical Biology Institute, La Jolla, CA, 1983-1984. Participant in the USA-Japan Eye Immunology Advisory Conference, November 27 to December 1, 1983, Honolulu, HI. Member, External Advisory Committee, Multi-purpose Arthritis Center, Duke University Medical Center, 1984-present. Member, Honorary Advisory Board, Italian-American Medical Association, 1984-present. Member, Peripatetic Club, 1984-present. Ex Officio Member, National Diabetes Advisory Board, 1984-present. Ex Officio Member, National Digestive Diseases Advisory Board, 1984-present. Chairman, Search Committee for Director, National Institute of Child Health and Human Development, 1984-present. Member, Department of Health and Human Services Task Force on Alzheimer's Diseases. The 1985 Albert Lasker

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Medical Research Award Jury. Deputy Ethics Counselor, Department of Health and Human Services, 1985-present. Member, Department of Health and Human Services Committee to Coordinate Environmental and Related Programs, 1985-present. Member, Scientific Organizing Committee, Joint Meeting of the Italian Society of Immunology and Immunopathology-National Institutes of Health on "Human Lymphocyte Activation," Florence, Italy, September 5-7, 1985. Member, United States Delegation to the United States-Japan Cooperative Medical Science Committee, 1985-present. Member, Scientific Seminar Subcommittee, National Institutes of Health Centennial Program, 1985-1987. Member, Advisory Board, Clinical Immunology Newsletter, 1986-1988.

Editorial Boards:

Dr. Fauci has been or is on the Editorial Board of 26 scientific journals in the field of immunology, allergy and infectious diseases. These include: The Journal of Clinical Investigation; The Journal of Immunology; Journal of Infectious Diseases; Journal of Clinical Immunology. Dr. Fauci is also the Editor of one of two major textbooks of medicine in the world, "Harrison's Principles of Internal Medicine."

Awards and Honors:

Alpha Omega Alpha. Kileen Prize for Excellence in Chemistry (College of the Holy Cross). John Metcalfe Polk Prize for General Efficiency (Cornell University Medical College). Alfred Mortitz Michaelis Prize for Efficiency in General Medicine (Cornell University Medical College). U. S. Public Health Service Meritorious Service Award, 1979. Arthus S. Flemming Award, 1979 -Given to the 10 outstanding employees in the U. S. Federal Government. Squibb Award of the Infectious Diseases Society of America, 1983. U. S. Public Health Service Distinguished Service Medal, 1984. 1985 Citation Classics (Current contents) for article - A. S. Fauci, D. C. Dale, and J. E. Balow: Glucocorticosteroid therapy: mechanisms of action and clinical considerations. Ann. Intern. Med. 84: 304-315, 1976. Who's Who in America, 44th Edition. Who's Who in Science and Technology, 2nd Edition. 1985 Stanford University Center Survey of the American Rheumatism Association membership ranked the work of Dr. Anthony S. Fauci on the treatment of polyarteritis nodosa and Wegener's granulomatosis as one of the most important advances in patient management in rheumatology over the past 20 years. Professor of Medicine at a large number of major medical schools throughout the country.

Publications:

Dr. Fauci has authored over 500 scientific publications in the field of basic and clinical immunology and infectious diseases.

INTRODUCTION OF ASSOCIATE

Dr. FAUCI. On my left, Mr. Chairman, is Ms. Yvonne du Buy, the budget officer of the National Institute of Allergy and Infectious Diseases.

I have submitted, as you mentioned, my written statement for the record, and I would like to spend the next minute or so outlining for you certain areas of interest and importance to our Institute's research.

As you may recall, when I appeared last year before you and this committee, I discussed the importance of basic biomedical research, particularly in the areas of immunology and infectious diseases, and how this basic research would have an important impact on and practical implications for the National Institute of Allergy and Infectious Diseases.

I am pleased to report to you today that a number of major advances have been made in these research areas as a result of this particular strategy. For example, using the technology of recombinant DNA, we have been able to obtain, in highly purified form, a number of substances that are critical to the regulation of the immune system, and thus to health and disease. These include the interleukins and the interferons. You have heard from Dr. DeVita about the use of interleukin–2 in cancer patients. That is one of the mechanisms through which we are attempting to reconstitute the immune response in AIDS patients. This approach would not have been possible if we had to rely on the natural production of this substance. The same holds true for the interferons, particularly gamma and alpha interferons, both of which are used to regulate the immune response, in combination with chemotherapeutic agents in the treatment of AIDS and cancer patients.

In addition, we have made major advances in tissue typing, which has important implications for organ transplantation. Furthermore, a number of components and products of microbes, obtained by recombinant DNA technology, have been made available in highly purified form. These are potentially useful as vaccines in a number of diseases of great importance throughout the world. One of these is malaria. You heard from me last year how difficult it was to produce a vaccine for malaria because of the difficulty of growing large amounts of the parasite. Likewise with regard to hepatitis B, I pointed out how difficult it is to produce the vaccine because the source of it was plasma from infected individuals. Now, in both cases, we have the highly purified components through recombinant DNA techniques.

In addition, a great deal of concern has been expressed regarding some of the toxic side effects of the pertussis vaccine. One of the ways that we can avoid these effects is to use the highly purified products produced from recombinant DNA material.

Finally, and most recently, as I discussed with you just a few moments ago, we have the possibility for a vaccine against the acquired immunodeficiency syndrome. This concludes my oral statement, Mr. Chairman. I would be happy to answer any questions that you have.

MALARIA VACCINE

Senator WEICKER. Thank you very much.

Where do we stand on malaria? Have we made quite a bit of progress toward a vaccine in that area?

Dr. FAUCI. Yes; you may remember from last year, I told you about a possible circumsporozoite vaccine. We have used molecular genetics to get the gene of the malaria parasite which codes for the particular outercoating of this sporozoite. Sporozoite is a strange word that just refers to one of the stages of the malaria parasite life cycle. Two vaccines have been prepared since I spoke to you last year, and these are ready for safety and immunogenicity testing in volunteers.

In addition, last year I briefly alluded to another strange word called the merozoite phase of the parasite, which is the phase of the malaria parasite that attacks the red blood cells. Studies on the ability of these antigens to protect against disease are also underway. Thus, we really have made some significant progress since I presented this to you last year.

OTHER IMPORTANT ADVANCES

Senator WEICKER. In addition to the progress that you have cited, are there any other areas where there have been significant developments in the past year?

Dr. FAUCI. There have been a number of areas. You have already heard of some with regard to AIDS.

We have had some important advances in transplantation immunology, particularly using recombinant DNA techniques to elucidate the antigens that are responsible for the rejection of organ transplants. Based on these techniques, we have the precision to be able to closely match organ donors and recipients. This has led to an extraordinary increase in the success of organ transplantation.

In addition, I mentioned the hepatitides in my opening statement. There are three major hepatitis viruses that cause disease in this country. They are hepatitis B, which we have spoken about in the past, hepatitis A, and non-A, non-B hepatitis. For both hepatitis A and hepatitis B, we are testing second generation vaccines. We have cloned the virus and through recombinant DNA techniques gotten proteins which appear very promising for hepatitis vaccination.

There is a reluctance in this country to utilize the currently available hepatitis B vaccine for a number of reasons. For one, it is very expensive, because the process involves purification of large amounts of human plasma to isolate the hepatitis B virus surface antigen. With the new recombinant DNA technologies, such antigens will be available in highly purified forms and in great quantities.

Another area in which there have been significant developments is the dissection of the immune system. I spoke to you about this last year. Now we can manipulate and regulate the immune system to give us a handle on diseases that are characterized by too much immunity such as hypersensitivity, as well as too little immunity, such as acquired immunodeficiency syndrome.

Finally, I should mention antiviral therapy. We have made some very important advances in antiviral therapy, not only regarding AIDS, but also for viruses that are really unrelated to AIDS. I will give you one very brief example. Herpes simplex encephalitis is a very devastating disease. It is caused by the same virus that causes cold sores on the mouth and that causes genital herpes. This virus can also cause a very severe encephalitis. In the past, the associated mortality figures were absolutely astounding. Prior to any available therapy, there was a 70-percent mortality from herpes simplex encephalitis. Of the survivors, only 2.5 percent of them returned to normal neurological function.

A couple of years ago we tested an antiviral drug called vidarabine. Treatment with vidarabine brought the mortality down to about 44 percent. Most recently, as published in the New England Journal of Medicine a few months ago, we have now compared vidarabine with the new antiviral drug, acyclovir. With acyclovir treatment, mortality is down now to about 19 percent, with a striking 38 to 45 percent of surviving individuals returning to normal function. This is a major advance in a very, very difficult area, and that is just one example of advances in antiviral therapy.

ACELLULAR PERTUSSIS VACCINE TRIAL

Senator WEICKER. We understand that the Swedish trial of a safer pertussis vaccine is now underway. Will this trial provide you with the information necessary to make new vaccine available to the public in the shortest possible time?

Dr. FAUCI. In this vaccine trial, which actually started on February 3, 1986, we are testing two acellular vaccines. By acellular, we mean that we do not inject the whole pertussis bacteria into the child, but instead only certain components of the bacteria.

A lot of the problem associated with the whole cell vaccine is that certain toxins would cause fever and other types of difficulties. These acellular vaccines are now being tested. While we have indications that these vaccines will be safe and effective, we will not be certain until we actually do the testing. If they do prove effective, that would be a major advance toward the use of these types of acellular vaccines in this country.

BUDGET CUTS

Senator WEICKER. Is there any particular aspect in your operation that you feel is being excessively impacted by the cuts imposed? Is there any area of particular concern within your budget that is going to be shortchanged, or where a priority is being shortchanged?

Dr. FAUCI. As with all of the other institutes, Mr. Chairman, we have had to make some choices and set some priorities with regard to work going on in the Institute. Reviewing our budget, we generally would divide it into what we call investigator-initiated mechanisms, which include centers and research project grants, and more directed research such as contracts.

We have had to cut contracts and are going to take a good, hard look to make sure that we fund those of the highest priority. Hopefully within the scope of those activities funded, we will be able to get the best research accomplished. But that is an area that I am a little concerned about because it involves research such as the vaccine development and accelerated development of new vaccines programs, much of which is supported through the contract mechanism. We will try our best to make do with what we have.

Senator WEICKER. What is this specific area, and what is this item on the budget that we are talking about?

Dr. FAUCI. We are talking about the contract mechanism, research and development contracts.

Senator WEICKER. Would your budget officer show me exactly what item that is.

Ms. DU BUY. It is the R&D contract line where we are showing $15,235,000.

Dr. FAUCI. It is about four lines up from the bottom on the mechanism table, where it says $15,235,000.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. All right, Dr. Fauci, I have further questions for response to the record. I thank you very much for what you are doing in your Institute and your coordination of the AIDS project.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

AIDS - CENTRALIZATION OF FUNDING

Question. Dr. Fauci, I understand that you have been identified as the coordinator for AIDS-related research at the NIH. How will you interact with the Office of the Assistant Secretary for Health?

Answer. As coordinator for AIDS research for NIH, I represent NIH, along with Dr. Wyngaarden, on the PHS Task Force on AIDS, which has operated out of the Office of the Assistant Secretary for Health for several years. The Task Force meets every two weeks and is responsible for overall coordination of PHS efforts in AIDS research. Procedures for interaction with the Office of the Assistant Secretary for Health after the proposed consolidation will be determined at a later date.

Question. What will be the impact of having AIDS funding under the control of OASH?

Answer. There are clearly advantages and disadvantages in having AIDS funding in OASH. While it will provide for greater flexibility for the OASH, it may make it more difficult initially to plan and implement research activities in a timely fashion at the Institute level. The difficulty is associated with the uncertainty of knowing precisely when and what funding will be made available to the Institute.

Question. Will this have any impact on intramural research efforts already underway?

Answer. The AIDS funds in OASH reflect support for salaries, supplies, equipment, etc. for intramural investigators currently engaged in AIDS research. Thus, the Intramural Research Program would be affected if the anticipated reimbursement is not received.

Question. Will this have any impact on the non-competing or ongoing extramural efforts in AIDS research?

Answer. We have received verbal assurance from the OASH that commitments will be honored through the reimbursement process. If, for some reason, funding is not received for noncompeting extramural awards in AIDS research, the costs associated with these activities would be supported at the expense of new and competing renewal awards in AIDS.

Question. In addition to your intramural AIDS efforts and extramural AIDS research commitments, will placing funds in OASH affect other non-AIDS research efforts?

Answer. Other research efforts could be affected only if the requested authority to permit the Secretary to transfer up to 1 percent of funding from non-AIDS to AIDS research is approved and exercised. It is possible that 1 percent of the NIAID appropriation could be transferred from the Institute to other PHS components. It is also possible that the NIAID could receive additional funding through the transfer authority; these funds would be directed toward

AIDS research and therefore would have no effect on other Institute programs.

AIDS - FULL TIME EQUIVALENTS

Question. The FY 1986 appropriation for your Institute included additional money for new research initiatives in AIDS. Do you have sufficient personnel to adequately implement and administer these new initiatives?

Answer. The original FY 1986 President's budget reflected $22,450,000 for AIDS research for which NIAID received no additional FTEs but met this responsibility by shifting personnel from other research areas. The amended President's Budget for FY 1986 provided an additional $4,617,000 and 11 FTEs. The NIAID has, to date, assumed the responsibility for approximately $61,430,000 in research efforts for AIDS in FY 1986 with an additional 11 FTEs for AIDS, and a concomitant reduction in non-AIDS FTEs of 43 from the 1985 actual usage. The additional staff for AIDS, together with personnel redirected from other research areas, will make every effort to effectively and efficiently implement and administer these major research initiatives.

Question. Has other research been slowed or stopped because of transfer of personnel to AIDS research?

Answer. Since the NIAID AIDS research effort began, approximately 46 FTEs have been redirected from other research areas into AIDS research. These redirections have included laboratory and clinical personnel previously working in areas such as hepatitis, various immunologic disorders, and infectious diseases, as well as researchers in basic immunology and microbiology. In addition, health scientist administrators and grants and contracts management staff have become increasingly involved in work related to AIDS.

AIDS - "MASTER SWITCH"

Question. I have recently read about a "master switch" in the AIDS virus. Please bring us up to date on the status of this research involving the genetic component of the AIDS virus and how it controls the spread of the virus throughout the body's cells.

Answer. The "master switch" you refer to is the discovery of the TAT gene in the AIDS virus. The initials "TAT" stand for Trans-Activating Translation or Transcription. The TAT gene codes for the expression of a protein, also called TAT. In the case of the HTLV-III/LAV, the TAT protein causes the translation or synthesis of viral proteins and other cellular genes to be expressed. The pathologic consequences of the AIDS virus are seen primarily when the virus replicates and produces new virus particles. When the TAT gene is expressed by a latent AIDS virus, it causes other cellular genes to be expressed, in particular the cellular gene which codes for the protein that serves as the receptor for the AIDS virus. When this occurs, the AIDS virus has more cells to infect in the body, and consequently more virus is produced with a corresponding increase in the pathology of the disease. When the TAT gene is not expressed, the AIDS virus remains

latent or dormant in the infected cell so that the control of the expression of TAT does have consequences for the host.

Question. What might this discovery mean in terms of treatment of AIDS patients?

Answer. If this expression could be controlled by a specific drug, for example, the infection might be kept in this dormant or latent state indefinitely. The TAT gene then is an appealing target for antiviral development because it is found only in viruses such as HTLV-III/LAV. This is potentially a very important observation, and more research needs to be done to clarify the role of the TAT gene in the development of disease in AIDS patients and to define more clearly the potential for control of this infection by interdicting the expression of the TAT gene.

AIDS - SPREAD

Question. How confident are you that the AIDS virus cannot spread through casual contact with victims?

Answer. We are quite confident that the AIDS virus cannot be spread through casual contact. This question has been looked at very carefully not only in family units but among health care providers caring for AIDS patients. The virus simply is not easily transmitted other than by sexual routes or by direct exposure to contaminated blood or blood products. Furthermore, the virus does not survive well on environmental surfaces such as tables, chairs, skin, and clothing. Everyday, non-sexual contact with an infected person living in the same house, for example, does not lead to infection.

Question. Are you supporting any long-term studies of family contacts with AIDS patients?

Answer. We are supporting several long-term studies of family contacts with AIDS patients. Most of these studies involve the long-term follow-up of children who have been infected through their mothers or because they are hemophiliacs and were exposed to the AIDS virus as part of their treatment. Two studies in particular, one in Miami (Parks) and one in New York City (Rubinstein), are actively involved in the follow-up of pediatric patients. More research needs to be done in this area since the natural history of this disease may be quite different in children. We need to know how it differs from a clinical, virological, and immunological viewpoint. In addition, treatment of AIDS and related conditions in these patients needs to be investigated.

Question. How can we dispel public fear of contact with AIDS patients?

Answer. Public fear of AIDS is generated because people do not understand the disease very well, and they know it is assumed to be fatal. Two things must be done to dispel this fear. First, more research needs to be done on this disease so we can better understand who is at risk and why. Second, the results of these research findings must be regularly and responsibly shared with the public, so they are adequately informed about the risks and can make

sound judgments about their risk of infection and disease. The NIAID sponsors regular meetings with health care providers and the lay community to describe the problem and to bring new information to the public regarding new research findings and other information so that the public can deal with this situation in a reasonable manner.

AIDS - PRESENCE IN SALIVA

Question. I have read recently that AIDS antibodies can be found in patients' saliva. Does presence of antibodies in saliva mean that saliva can spread the disease?

Answer. The presence of AIDS antibodies in the saliva of an individual means only that this person has been infected at one time in his life and has responded to the infection by producing antibodies to the virus. It does not mean that the individual is infectious. Antibodies, which are produced by the body as a result of infection by any microorganism, are commonly found in saliva; but they do not indicate whether the person can transmit a particular disease. In studies of nonsexual household contacts, such as people who shared drinking glasses or food, AIDS transmission has not been found to occur. Saliva from some individuals infected with the AIDS virus has been found to contain antibodies to the virus, and in some cases their saliva contains the virus itself. It remains to be seen how often saliva from infected individuals contains the virus or whether, even if the virus is present, it can transmit the disease through this route. Further research is needed to answer these questions.

SEXUALLY TRANSMITTED DISEASES

Question. Is your Institute planning any new initiatives in the area of other sexually transmitted diseases or has this area been overshadowed so much by AIDS that activity in other sexually transmitted diseases is decreasing? Genital herpes? Are you involved in any research on pelvic inflammatory disease?

Answer. The NIAID will continue support of its ongoing program in sexually transmitted diseases research. The activity currently supporting the AIDS program has not overshadowed the STD program.

Genital herpes research, as part of the overall STD program, will be continued and expanded whenever possible. For example, the Institute intends to support a new program project focused on research to understand the mechanism of latency in genital herpes infections. The Institute is also committed to an expanded research program on chlamydia infections; plans are under way to support a new program project (STD Research Unit) in this area. The Institute does have a modest research effort on pelvic inflammatory disease.

GRAMM-RUDMAN

Question. NIH has been required to absorb the 4.3% ($320 million) Gramm-Rudman cut in FY 1986 by budget mechanism. Does this present problems for the research institutes or does the lack of flexibility interfere with the Institutes' mission?

Answer. Although the 4.3 percent sequestration has been applied evenly across all programs and mechanisms at NIH, the Institute Directors have the authority and flexibility to reallocate funds within existing reprogramming rules to meet the most critical program objectives, as long as they do not deviate from the few programs, projects, and activities formally reported to the Congress under the Gramm-Rudman-Hollings procedures, and as long as NIH meets the congressional mandate to fund no fewer than 6,100 research project grants.

Question. How much direction and flexibility should the Director of a research Institute have in order to minimize the indiscriminate impact of across-the-board cuts?

Answer. In my opinion, it would be preferable to absorb the cut at the appropriation level. In that way, each Director could apply the reduction in such a way as to maintain program balance and protect high priority programs.

Question. If you had the flexibility to allocate the reductions among your programs in another way, would you shift these funds?

Answer. We will request reprogrammings if we consider that shifts would be appropriate.

Question. Please explain why your choice of distribution would produce better management results?

Answer. I believe that the management of the Institute is consistently excellent. Choice of distribution would have the greatest benefit for the NIAID research programs, enabling us to support the highest priorities and to respond to emerging opportunities as they occur.

IMPACT OF BUDGET REDUCTION

Question. The President's budget proposal for FY 1987 reduces your budget by $25,834,000 under FY 1986 appropriated levels. Gramm-Rudman-Hollings, if triggered, could reduce your budget even further--maybe as much as 20 percent. I've known this would reduce the number of grants, possibly the size of grants, centers, training, etc., etc. Can you give us some idea of the impact of these reductions on the kinds of research that would be stopped or lost?

Answer. The President's Budget was developed within overall deficit targets that would preclude the need for any 1987 sequestration. If the magnitude of reductions you mentioned were necessary, the NIAID would make every effort to honor its commitments to the extramural community, thus necessitating considerable reductions in, or possible elimination of, numerous programs and new starts.

Question. What impact might this have on the health of our citizens five and ten years down the road?

Answer. It would certainly retard the development of new methods of treatment and prevention for a number of infectious and immunologic diseases which, because of recent dramatic advances in biomedical technology, are feasible and imminent.

Question. Can you discuss your contingency plans if these massive budget cuts should come to pass?

Answer. We do not have contingency plans at this time.

AIDS - REPROGRAMMING PROBLEMS

Question. How much money will your Institute receive specifically earmarked for AIDS research in FY 1986?

Answer. An additional $4,617,000 was identified for AIDS research in the amended President's Budget, and a planned allocation of $35,527,000 from the Office of the Director, NIH, is slated to be reimbursed to the Institute before the end of the fiscal year.

Question. How much money will you spend on AIDS research in FY 1986?

Answer. Within NIAID's FY 1986 appropriation, together with the planned reimbursement from the Office of the Director, NIH, we will obligate an estimated $61,430,000 for AIDS research in FY 1986.

Question. How much of this money had to be taken or reprogrammed from other activities, functions or programs?

Answer. It is not possible to estimate precisely the level of resources that have been redirected to AIDS research. Over the years, we have appropriately shifted resources to AIDS as we recognized its importance as a major infectious disease.

Question. For the record, please list all activities, functions or programs that were raided for this purpose and describe the specific impact on each. Please provide the Committee the same information for personnel changes caused by an FTE shortage in the areas of AIDS-related research.

Answer. This redirection has impacted upon, to varying degrees, all the research areas supported by the Institute. Since the Institute has been redirecting its resources into AIDS since FY 1982, we cannot identify the specific impact on each activity that has been affected by this redirection. The efforts of individuals in both the intramural and the extramural program, whose expertise was closely related to the scientific requirements of AIDS research, have been redirected to AIDS. Among the areas that have been affected are the following: hepatitis, slow virus diseases, basic molecular biology, immunoregulation, immune disorders, mucosal immunity, parasitic diseases, sexually transmitted diseases, epidemiology on Lyme disease and enteric diseases, antivirals for influenza, genital herpes, genital warts, encephalitis, influenza and other respiratory viral diseases.

NEW ADVANCES VS. INADEQUATE BUDGET

Question. Last year the NIH report on immunology indicated that advances have been made which presented opportunities for new

research initiatives. Will your present budget request allow you to undertake these initiatives this year?

Answer. The explosive growth of knowledge in basic immunology and its clinical aspects that has occurred over the past few years is continuing to provide breakthroughs in several areas. As reported in the NIH Report on Immunology Research, which was submitted to the Committee on Appropriations in February 1986, this newly acquired knowledge offers exciting opportunities to improve diagnosis, treatment, and prevention of a variety of immunologic diseases and disorders. The budget request will allow us to support the highest priority projects among the many available to us.

Question. Can you give us an example of an initiative that will not be pursued, and speculate on the long-term impact of not following that particular avenue of research.

Answer. In addition to decreasing by four the current number of Asthma and Allergic Disease Centers and reducing by 30 percent the remaining 14 centers, the NIAID will not establish new centers for study of adverse drug reactions and for study of occupational immunologic lung diseases. Also deferred are plans to address some important and distressing problems for asthmatics, such as sensitivity to aspirin and sulfite additives in food preparations and to establish core outreach components in each of the CIRIDs.

Similarly, the solicitation of multidisciplinary program projects to study childhood immunodeficiency disorders and the interaction of the immune system with the neural and endocrine systems will be postponed. With the former, opportunities now exist to improve bone marrow transplantation as a treatment modality for inherited as well as acquired defects in immune function. The influence of immune system function on the pathogenesis of multiple sclerosis, myasthenia gravis, juvenile diabetes, and other physiologic systemic disorders also is an area ripe for further initiatives.

In the field of transplantation immunology, activities to be postponed include the establishment of multidisciplinary program projects: to study new approaches to prolong organ graft retention; to develop and acquire histocompatibility typing reagents; and to study the mechanism of cyclosporine's immunosuppressive action.

Fundamental studies of the immune system's structure and function also will be affected. Plans to increase research grant funding of studies of the life cycle of antibody-producing B lymphocytes to enhance understanding of their differentiation, growth, and functional reactivity and to acquire the capability to manipulate them selectively in a clinical setting will be postponed.

The long term impact of not following these avenues of research will be a delay in acquiring new information important for disease prevention and treatment.

VACCINE DEVELOPMENT

Question. I understand that the Institute of Medicine has completed its report assessing the need for new vaccines for

domestic use. Have they also completed a similar report on international vaccine needs?

Answer. The report on international needs has been completed; its publication is waiting final approval of the National Academy of Sciences.

Question. What vaccines were recommended as top priority for research?

Answer. For international use, the Institute of Medicine (IOM) assigned highest priority to the following five vaccines in the order listed:

Streptococcus pneumoniae (protein-polysaccharide conjugates)
Rotavirus
Malaria (Plasmodium falciparum sporozoite)
Salmonella typhi (typhoid)
Shigella (bacillary dysentery)

For domestic use, the Institute of Medicine assigned highest priority to the following five vaccines in the order listed:

Hepatitis B virus (HBV, recombinant DNA-derived)
Respiratory syncytial virus (RSV, live attenuated)
Haemophilus influenzae, type b (Hib)
Influenza (live attenuated)
Varicella (immunocompromised children)

Question. What are your plans in reacting to the Institute of Medicine recommendations?

Answer. NIAID targeted nine of these ten vaccines when it initiated its Program for the Accelerated Development of New Vaccines in 1981. NIAID did not list pneumococcal vaccine because a licensed 23-valent vaccine for the prevention of pneumococcal pneumonia was available in the United States. Like other polysaccharide vaccines, this vaccine is poorly immunogenic in young children, and it is young children who are at high risk of morbidity and mortality from pneumococcal infections in the developing world. Thus, the IOM recommended that attempts be made to conjugate pneumococcal polysaccharides with a protein carrier, as is now being tested for H. influenzae type b, for use in young children. NIAID and U.S. Agency for International Development jointly sponsored a Workshop on Pneumococcal Vaccines for Developing Countries on March 10 to make plans for implementing the IOM recommendations.

A vaccine on the NIAID list, but not on the IOM list, is an improved pertussis vaccine. This is because the IOM Committee recognized that efforts were already under way to accelerate the development and testing of such a vaccine.

As for the other vaccines, varying degrees of progress have been made. An H. influenzae type b polysaccharide vaccine for the prevention of meningitis in children over 2 years of age has now been licensed; a conjugate polysaccharide vaccine for use in younger children is now being tested for efficacy in Alaska. It is expected that varicella and hepatitis B recombinant virus vaccines will soon

be licensed. Rotavirus vaccines are undergoing tests for efficacy in the United States and abroad. Two genetically engineered malaria (P. falciparum sporozoite) vaccines are ready for early testing in man. A malaria vaccine evaluation center is soon to be established to facilitate the testing of antigens from other stages of the P. falciparum life cycle and from other species such as P. vivax. Genetically engineered Salmonella and Shigella bacteria are being tested in volunteers as live attenuated oral vaccines.

Question. What is the impact of the FY 1987 budget request on your program for the development of new vaccines?

Answer. The development of vaccines beyond basic laboratory studies relies heavily on targeted research funded by the R&D contract mechanism. The reduction in contract funds in FY 1987 will decrease the number of volunteers that can be studied in the two units funded for that purpose and will decrease the number of vaccines that can be subjected to Phase I testing in our four Vaccine Evaluation Units. A field trial to test the efficacy of rotavirus vaccine on a Navaho and Apache Indian reservation will be terminated before the desired follow-up observations have been made. Nevertheless, efforts will be made to support the highest priority research.

Question. In your professional judgment, what should be done to assure a sustained level of vaccine development to respond to the public need?

Answer. It is my professional judgment that a sustained level of vaccine development depends on an effective partnership between Government and industry. The Federal Government support for biomedical research, through the NIH grants program, must continue its funding of the basic research that has contributed such tools as recombinant DNA and hybridoma cell technologies. The intramural laboratories of NIAID and other NIH Institutes working on experimental vaccines must have stability in terms of staff and resources. R&D contract funding in NIAID's extramural program is needed to support scientists to work on promising new vaccines. Finally, successful commercial production and distribution are essential to appropriate utilization, and these require a healthy biologics manufacturing industry.

PERTUSSIS VACCINE

Question. We understand that the Swedish trial of a safer pertussis vaccine is now underway. Will this trial provide you with the information necessary to make the new vaccine available to the public in the shortest possible time?

Answer. NIAID is currently supporting an acellular pertussis vaccine efficacy trial in Sweden to determine the reduction in disease due to pertussis among recipients of the new acellular vaccine(s) compared to control children of the same age groups who will receive a placebo. The study will also attempt to evaluate the correlation between protection and protective antibody responses and assess the incidence of adverse reactions with the new vaccine(s).

If the efficacy studies in Sweden demonstrate a pertussis vaccine to be protective, the data would be of great assistance in guiding the formulation of other candidate vaccines.

Additional clinical studies may be necessary for a number of reasons, including the need to examine different adjuvants (a vaccine component which heightens immune response), or to further evaluate the safety of a given product. At present, our understanding of the basis of immunity to pertussis is incomplete, and we are not able to identify conclusively which antigens must be included in a vaccine to ensure protection. Clinical trials to demonstrate that a vaccine actually protects against disease is the only available method to select vaccines for use. Such trials, to show if acellular vaccines are effective, and which can provide some laboratory test that can be correlated with clinical protection, are considered essential in the development of acellular vaccines.

The results of our current efforts are likely to provide an effective pertussis vaccine that will produce fewer local reactions and less febrile response.

We must emphasize that, despite scientists' best efforts, there are no guarantees in research. If progress is slowed by unexpected developments, or if the new vaccines prove not to be as effective as hoped, additional years of effort might need to be expended. Even with the demonstration of safety and efficacy and the licensing and use of the new vaccines, there will be a need for post-marketing studies to determine the duration of vaccine immunity and the incidence of rare adverse effects. No vaccine can be expected to be completely free of side effects, and it should be recognized that coincidental events will continue to occur. Thus, liability and compensation problems will remain with any new products.

Question. In your professional judgment, will additional information be required to accelerate the development of a new vaccine?

Answer. Attempts to prepare improved pertussis vaccines have a long history, spanning more than 40 years. This work has involved studies by individual investigators, state and Federal government scientists, and many manufacturers here and abroad. Major modern efforts have been directed toward the development of acellular, rather than whole cell, vaccines. The investigations have focused on identifying and purifying the bacterial components that may be associated with protection from infection in animal models, on understanding the mechanisms by which some of the biologically active components act in vitro and in vivo, and on their safety and immunogenicity in humans.

Although there is great interest in clinical trials of the acellular pertussis vaccine to establish safety and efficacy, it is clear that research in other areas must continue. Once the immunogens have been identified, studies to produce them by classical methods, genetic engineering, or synthesis will be necessary. The manner in which a vaccine is used is important. There is a need to examine the time and age of immunization so as to reduce risk, optimize immunity in susceptible individuals, and protect those at greatest risk. Laboratory studies, coupled with

research to optimize dose and immunization schedules, will require an expenditure of additional efforts and resources.

Question. Are you requesting the funding necessary to complete this process, and if not, how much more resources will be necessary in FY 1987?

Answer. Within the funds available in the FY 1987 request, we will support all ongoing work related to pertussis including the trial in Sweden. The development and evaluation of new, improved vaccines is a major priority of both Government and private sector groups; vaccine manufacturers commit substantial resources to this goal. Several PHS agencies, particularly NIH, CDC, and FDA, have major programs to support the development and evaluation of improved vaccines. The development of safe and effective childhood vaccines is a long-term effort and will require continued commitment of resources.

CENTERS

Question. Your FY 1987 budget submission indicates a 30 percent reduction in recommended funding levels for research centers and a decrease of four centers from FY 1986. I understand that research centers are an efficient method of supporting similar research and serve to bring together talented scientists under one roof. Why are your asking for a reduction in the number of centers, and why are you cutting support for the surviving 14?

Answer. Within the funds available in the FY 1987 budget, an attempt was made to maintain balance between investigator-initiated research and more targeted or applied research. Since 70 percent of the Institute's budget was directed to investigator-initiated research project grants, the centers category was necessarily reduced to a significant degree.

TRAINING

Question. The FY 1987 budget proposal reduces the number of trainees by almost 800. What effect will this have on your training program?

Answer. The FY 1987 budget reflects a reduction for the NIAID of 88 full-time training positions from the FY 1986 comparable level of 463, giving a total of 375 positions for FY 1987. Thus, opportunities to attract young investigators into the fields of basic and clinical immunology and microbiology will be reduced.

Question. In your professional judgment, what would be an optimal level of training, given the scientific talent available in this country?

Answer. In my professional judgment, an optimal level of research training for NIAID would be the support of 600 full-time training positions in areas relevant to the mission of this Institute.

Question. Countries in Western Europe and the Japanese have revitalized their biomedical research programs. In your

professional judgment, what will be the long-range effect on our abilities to remain the leaders in biomedical research if we continue to reduce the number of training programs supported by NIH?

Answer. If reductions in the number of trainees supported by NIH continues to decline, medical advances and biomedical breakthroughs in the United States may diminish. This could place the United States at a disadvantage in its competition with Western Europe and Japan. The training of a new generation of investigators is considered to be the lifeline of basic and clinical research and provides a continuous influx of new ideas and innovative approaches to the diagnosis, treatment, and prevention of disease.

FLU

Question. Are we having a serious influenza epidemic this year?

Answer. Yes, we are having a serious epidemic of influenza. Two types of influenza viruses are responsible, a type B virus and a type A virus. The type B viruses have predominated. It has now been reported that the percentage of pneumonia and influenza deaths recorded in 121 U.S. cities has exceeded the statistical limit for non-epidemic periods for eight consecutive weeks. This means that this epidemic is the most severe we have had since 1980-81. The current epidemic, however, appears to be ending.

Question. Dr. Fauci, you have told us in the past that vaccination programs are the primary means of fighting epidemics of this type. Will your present budget and the proposed FY 1987 budget have any effect on your program to develop effective influenza vaccines?

Answer. Vaccination is the best way to prevent influenza epidemics, particularly in the high-risk population groups--that is, persons with underlying chronic heart, lung, cancer, or metabolic disease. In addition, persons over age 65 are at risk for serious influenza. The NIAID has emphasized influenza in its research program because of the serious nature of the periodic epidemics that strike our population. We have endeavored to develop improved methods of providing immunity against influenza viruses. One approach has been to use an attenuated, live vaccine. We believe that this approach has much to offer because it may provide a longer lasting immunity that may protect against new strains of the virus. In this way the vaccine might not have to be administered every year. In addition, the vaccine is administered by nose drops, and we believe it will be easier and simpler to use.

In FY 1987, the influenza vaccine program will be continued, but at a somewhat reduced level. For example, each of four vaccine evaluation units which test various experimental vaccines, including influenza vaccines, will be reduced. In addition, a reduction is proposed in the operation of an Influenza Research Unit. The number of clinical studies with newly developed influenza vaccines, therefore, will be reduced, as well as laboratory and surveillance studies for evaluating methods of prophylaxis and therapy.

BRINGING NEW ADVANCES TO THE PUBLIC

Question. I understand that the transfer of new advances and new technology to health care providers is of great benefit to our citizens. What is the status of these outreach programs--especially the program concerning AIDS?

Answer. Since 1984, the NIAID outreach and technology transfer program has conducted conferences on AIDS for primary care physicians, health care workers, and service personnel in eight U.S. cities with repeated conferences in Los Angeles and Washington, D.C. These conferences have been very well received. Another Washington, D.C. conference, which will emphasize AIDS in minorities, is planned for April 1986. The outreach program also supported a conference on pediatric AIDS and partially supported the International Conference on AIDS in Atlanta in April 1985. The program has arranged for and supported travel of NIH staff to speak at professional and lay organization meetings and organized a workshop on AIDS for the 1985 meeting of the National Medical Association.

The outreach program has also supported conferences on lupus erythematosus, childhood immunodeficiency, immune system disorders, organ transplantation, and the immune system and neurologic disorders in various U.S. cities.

Question. Are you requesting sufficient funding in your FY 1987 budget to allow these outreach programs to function efficiently and to reach the maximum number of people?

Answer. With the proposed reimbursement from OASH to NIAID, the funds for outreach contained in the President's FY 1987 budget will allow for maintenance of the outreach program for AIDS at approximately the current level. We will be able to sponsor conferences for health care providers and service personnel at a rate of one conference every 2 to 3 months. Assuming the proposed reimbursement from OASH to NIAID, we think we would reach approximately 8,000-10,000 health care providers and service personnel. Outreach efforts in non-AIDS areas of the Institute's mission will be minimal and conducted through our CIRIDs Program.

Question. How much funding would be necessary to achieve this goal?

Answer. The goals outlined above would be met within the level of $1,294,000 reflected in the proposed reimbursement from OASH.

AIDS - EXTRAMURAL FUNDING

Question. We have received several letters expressing concern that the new funds for AIDS research have not gone to the extramural scientific community in the form of research project grants. Can you address this concern and tell this Committee which mechanisms are being utilized to include the extramural community in the AIDS research efforts?

Answer. Of the $61,430,000 estimated to be obligated by NIAID for AIDS research in FY 1986, a total of $48,290,000 or 78.6 percent will fund extramural awards, including research project grants,

research centers, research career awards, other research related grants, research training, and R&D contracts.

AIDS - MINORITY VICTIMS

Question. We understand that the numbers of AIDS cases in blacks and hispanics is out of proportion to their representation in the U.S. population. Are you making any special efforts to deal with minority victims of this disease?

Answer. Of the total number of AIDS cases in the United States, approximately 25 percent have occurred in the hispanic and black populations. While this is larger than the proportion of blacks and hispanics in the U.S. population as a whole, the proportion of hispanics and blacks afflicted with AIDS is actually no different than the proportion of blacks and hispanics that live in the metropolitan areas where AIDS is most common, such as New York City, Los Angeles, and San Francisco. If one excludes drug abusers, their sexual partners and Haitian immigrants, the proportion of blacks and hispanics with AIDS closely resembles their percentage of the total U.S. population.

We have taken steps to increase the awareness of AIDS through conferences directed toward minority audiences. One of these will be held in Washington, D.C in early April. Through conferences such as these we hope to be able to educate minority professionals and professionals caring for minorities with AIDS. In addition, we have taken every opportunity available to us to speak to minority organizations about AIDS. The National Medical Association has been particularly useful in helping us reach minority physicians and nurses regarding this important problem.

AIDS - TREATMENT ABROAD

Question. There has been a considerable amount of publicity about people with AIDS going to France for treatment with drugs such as HPA-23; announcements about the use of cyclosporin in France; patients going to Mexico to obtain drugs. This has given the impression that we are somewhat behind other countries in our research on treatment for AIDS. Is this true? If not, what can be done to correct this misinformation?

Answer. The United States is not behind other countries in research on treatments for AIDS. In both of the cited examples, the reports coming from France were somewhat premature; the cyclosporin announcement was especially premature in that only six patients had been treated and only for a very short time, and only two showed some indication of improvement. HPA-23 is now being tested in the United States and is, in fact, being evaluated in the Clinical Center of the NIH. No results are available to date that would suggest that this agent will rapidly improve the viral or immunological status in treated patients. The trial is ongoing at this time as are several other trials with other agents.

Clinical studies of a number of agents are being conducted around the country under a variety of funding mechanisms. Some are supported by the NIH, some by private drug sponsors. The NIAID is in the process of establishing a number of Treatment Evaluation

Units that will test promising agents in Phase I and Phase II clinical studies. An AIDS Drug Selection Committee has been established to review data on chemotherapeutic agents and will help advise and set priorities for AIDS drug development in the NIAID and NCI. Once this system of treatment units is active, agents will be rapidly evaluated in properly designed and controlled studies.

An announcement of the existence of the AIDS Drug Selection Committee has recently been made in a number of scientific publications, and this will serve to focus attention on the approach being used to pursue drug development. Currently, most AIDS patients consider treatment with any drug as better than none, and there is less concern about whether it has been proven to have any benefit. As more information becomes available concerning agents being studied, issues such as toxicity and efficacy are likely to become more commonly understood, and a more sophisticated awareness will develop.

AIDS - DRUG TREATMENT

Question. What are the prospects for having a drug or drugs for the treatment of individuals with AIDS?

Answer. AIDS as a clinical syndrome is the result of a number of events that begin with infection with the HTLV-III/LAV virus. The opportunistic infections that eventually cause death are due to profound immune deficiency caused by the loss of T4 helper cells that serve as the prime target of the virus. When these cells become depleted beyond a certain point, the entire immune system is affected. The rationale behind antiviral drug therapy is to reduce or eliminate the active replication of the virus, and thus the assault on the remaining T cells, in order to give the immune system a chance to recover. As we have learned from chemotherapy of other viral infections, however, a key factor is to treat as early as possible. In addition to drugs directed against the virus itself, it may also be necessary to develop drugs that will stimulate the recovery of the damaged immune system. Use of immunomodulating drugs such as interleukin-2 and/or reconstitution procedures such as bone marrow transplantation will probably have to be used in combination with antiviral agents in the treatment of AIDS.

Preliminary data give some encouragement that such a combination therapy will eventually be successful, but it is not possible to predict when an effective treatment will be available.

Question. What drugs are currently being tested? Planned for the future?

Answer. The following agents or approaches are currently being evaluated:

azidothymidine
ribavirin
Foscarnet
HPA-23
suramin
ansamycin
dideoxycytidine

dideoxyadenosine
interferon
interleukin-2

Only two, dideoxycytidine and dideoxyadenosine, have not yet been tested in man. Another 21 substances have been submitted for review by the AIDS Drug Selection Committee.

Question. What is your Institute doing in the development and testing of drugs for AIDS treatment?

Answer. The NIAID has established, in concert with the NCI, an AIDS Drug Selection Committee (ADSC). The purpose of the ADSC is to select and recommend promising drugs for study, to coordinate the clinical studies of these drugs, to review candidate drugs or other therapies, and to track and coordinate drug development activities at NCI and NIAID.

In addition, in spite of the limited number of staff and the fact that this is a new program which has had to develop quickly, several important extramural initiatives have been launched. Contracts to screen antiviral drugs in tissue culture and in animal model systems are in place now or will be soon. Funding for basic research, epidemiology, and pathogenesis has increased.

In conjunction with the NCI, the NIAID has issued a Request for Applications for National Cooperative Drug Discovery Groups (NCDDG/AIDS). These Groups will be designed to develop scientific approaches to the discovery of effective anti-AIDS treatment ranging from interference with viral replication or function to the maintenance or restoration of the immune response. The NCDDG/AIDS will bring together scientists in virology, molecular biology, immunology, biochemistry, medicinal/organic chemistry and pharmacology; and each NCDDG/AIDS will bring together a multidisciplinary consortium to design, synthesize, and evaluate, at the pre-clinical phase, treatment entities and strategies.

NIAID is currently establishing an interagency agreement with the U.S. Army Medical Research Institute for Infectious Diseases for mass screening of compounds with anti-HTLV-III/LAV activity. Several thousand compounds will be screened each year by this mechanism.

NIAID issued a Request for Proposals on November 8, 1985, for the establishment of 10 AIDS Treatment Evaluation Units to undertake the following:

Part A: Clinical, toxicological, pharmacokinetics, microbiological and immunologic studies of candidate drugs for the treatment of HTLV-III/LAV infections.

Part B: Treatment or prevention directed at malignancies and the opportunistic infections associated with HTLV-III/LAV infections.

It is expected that awards will be made in mid-summer 1986.

Question. How long do you think it will take before an effective drug or combination of drugs will be available?

Answer. That is an extremely difficult question to answer without making some specific assumptions. If this hypothetical drug were already known to exist and had been identified as having some in vitro antiviral activity, it would be evaluated in some in vivo animal model systems for efficacy. It would also be tested in animals to study its distribution and toxicity. If all information remained promising, it would enter Phase I clinical study to evaluate the safety and pharmacokinetics of the drug at various doses in humans. Phase II studies would continue to refine the dose level and schedule and also look for evidence of efficacy. Confirmation of efficacy would occur in larger Phase III trials. In the case of an overwhelmingly active, and relatively non-toxic drug, it is possible that efficacy could be demonstrated somewhere between 2 and 3 years from the time an agent was identified in the test tube. It must be pointed out, however, that no antiviral drug has ever been identified that acts like such a "magic bullet."

Combination therapy is likely to take the form of an antiviral drug combined with some therapy that will enhance or reconstitute the immune system. Such an approach will be developed based on earlier testing of each agent alone. If the combination is more effective than either agent alone, that will be shown by comparing it to the single agent. Though possible, it is unlikely that an agent will be effective in combination while having no activity at all on its own.

GRAMM-RUDMAN-HOLLINGS

Question. If the automatic provisions of Gramm-Rudman-Hollings are triggered in FY 1987, your Institute may well have its budget reduced by 20-25 percent. Have you prepared a contingency plan in the event Gramm-Rudman-Hollings becomes reality? If so, please send a copy of your plans to this Committee.

Answer. We do not have contingency plans at this time.

Question. If cuts of this magnitude become reality, how will they be distributed: intramural vs. extramural programs

Answer. Although cuts would be sustained in both intramural and extramural programs, an attempt would be made to maintain a balance between the two. However, it would be extremely difficult, if not impossible, to sustain additional substantial cuts of this magnitude without closing down some programs completely.

Question. Peer review system; Would the number of site visits be reduced?

Answer. Peer review site visits are now reduced to the minimum. Further reductions cannot be taken in this area.

Question. Would travel to NIH to study section meetings be affected?

Answer. Study sections that review individual research project grants are administered by the NIH Division of Research Grants, not by the individual Institutes. The NIAID does support peer review groups for the review of program project, conference grant, training grant and research center applications as well as R&D contract proposals. Peer review of these proposals will require continuation of the regularly scheduled meetings of these groups.

Question. Would NIH employees have to be furloughed?

Answer. Whether NIAID employees would have to be furloughed would depend upon the magnitude of reductions and the areas to which they were applied.

Question. What major programs would have to be cut back?

Answer. Reductions of this magnitude would impact on all the research activities of the Institute, including vaccine development and testing, antiviral drug development and testing, transplantation immunology, basic and clinical studies on immune system disorders, tropical diseases, and sexually transmitted diseases.

Question. Please list the research programs of the highest priority that should not be cut and why.

Answer. All the research programs supported and conducted by the Institute would have to be carefully reviewed before appropriate decisions could be made regarding the extent of reduction in some and the elimination of others.

SEAFOOD DIET

Question. We are aware of recent reports that a seafood diet or fish oils influence health and may modulate a number of disease processes. What is known about this and what research are you doing in this area?

Answer. A marine diet apparently protects Greenland Eskimos and Japanese fishermen from coronary artery disease. This discovery has resulted in a rapidly expanding interest in the role of so-called omega-3 polyunsaturated fatty acids in seafood, and how they affect important physiologic and pathologic processes in our bodies, such as thrombosis, atherosclerotic, immune, inflammatory and proliferative processes. NIAID specifically is interested in promoting research on how omega-3 fatty acids in fish oils and seafood affect immune regulation and host responses to inflammatory agents, such as allergens and disease-causing microbes. Omega-3 fatty acids in fish oils are metabolized by the body into leukotrienes, chemical messengers which may play an important role in modulating inflammatory and allergic responses in our bodies. It has been shown in animal studies that autoimmune disease may be diminished or prevented by feeding fish oils. These fish oils yield a chemical form of leukotrienes, which produce less inflammation than leukotrienes derived from land-based animal fat.

The possibility through dietary intervention of modifying inflammatory and immunologic disorders opens up new and fascinating directions for research on some of mankind's most chronic and

heretofore incurable ailments. For example, because inflammation of the airways is a prominent factor in asthma, can we decrease its severity by a fish diet? Such questions are being studied at our grant-supported immunology and allergy center in Boston. Other individual research grantees supported by the NIAID are also concerned with this subject and are attempting to identify the chemical components in fish oils and to define their role as anti-inflammatory agents. NIAID is also participating in a trans-NIH grant program on the "Biological Mechanisms of Omega-3 Fatty Acids in Health and Disease," advertised in a Program Announcement released by the NIH on December 6, 1985.

Well-conducted field trials on the role of fish oils in allergic and inflammatory disorders will enlarge our knowledge and create the basis for sound dietary advice--something which is always hard to establish.

Question Submitted by Senator William Proxmire

ADP

Question. Last year in a record response you indicated that you planned to let a contract for "Design and Development of NIAID ADP State-of-the-Art Plan in 1985" and that substantial initial recommendations were anticipated after the first 6 months of the project. Do you have those initial recommendations as yet and, if so, can you give us some idea of how much it will cost to fully implement an advanced automated data processing system at the Institute?

Answer. In order to develop a comprehensive workscope for the subject contract, the NIAID awarded two small purchase orders, one for the conduct of a physical inventory of current automated data processing equipment in the Instiutte, and one for the purpose of surveying user needs throughout the Institute. At the conclusion of these two projects, it was found that the Institute had already made some advances in upgrading its ADP equipment and that, further, numerous NIAID staff, whose primary responsibility was not in the ADP field but who were identified to have a considerable level of knowledge in this area, were available to participate in the development of an ADP plan.

In view of these findings and the fact that the planned contract project was estimated to involve a considerable expenditure of funds, a decision was made to capitalize on the existing Institute expertise in the development of a plan. Another factor that was considered was the ultimate cost of implementing a state-of-the-art system. It was determined that what limited funds might be available for ADP would be more effectively spent on the actual procurement of equipment and software than on the development of the plan by a contractor. Therefore, the NIAID established an ADP Coordinating Committee, comprised of employees from all areas of the Institute with knowledge and skill in ADP systems and functions. In lieu of a costly contract, this Committee was charged with the task of developing a state-of-the-art plan.

Since its establishment, the Committee has conducted in-depth reviews and feasibility studies of the latest technologies and

systems in the field of ADP. As a result, preliminary recommendations have been developed and presented to senior Institute staff, and the Committee is currently in the process of revising these recommendations into a final plan.

Based on preliminary recommendations, it is estimated that the cost to fully implement an advanced automated data processing system within the Institute would be approximately $1.6 million.

RESCHEDULING OF HEARING

Senator WEICKER. I see my friend Dr. Löe back there. Dr. Löe, would you be ready to go tomorrow morning in this group that I would like to have tomorrow morning?

Can you make your presentation tomorrow morning?

Dr. LOE. Sure, I will be happy to.

Senator WEICKER. I won't crowd the people who are coming in on Monday since we have an extra hearing. What I would like to do, Jim, is to do the National Institute on Aging, research resources, and then the National Institute of Dental Research tomorrow at 10 o'clock.

Dr. WYNGAARDEN. That is fine.

Senator WEICKER. That will take the pressure off of those who are appearing on Monday, since we have this extra day.

SUBCOMMITTEE RECESS

I thank you all very much. The subcommittee will stand in recess until 10 o'clock tomorrow morning.

[Whereupon, at 12:15 p.m., Wednesday, March 5, the subcommittee was recessed, to reconvene at 10 a.m., Thursday, March 6.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1987

THURSDAY, MARCH 6, 1986

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker, Specter, and Proxmire.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

NATIONAL INSTITUTE ON AGING

STATEMENT OF DR. T. FRANKLIN WILLIAMS, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

KARYN S. ROSS, BUDGET OFFICER, NATIONAL INSTITUTE ON AGING

OPENING REMARKS

Senator WEICKER. The subcommittee will come to order.

We will first hear from Dr. Franklin Williams, the Director of the National Institute on Aging. It is a great pleasure to have you with us, Dr. Williams. I might add the principal reason for my postponing yesterday's hearing to today was that I place such a great importance on your testimony and the work of your Institute.

Dr. WILLIAMS. Thank you.

Senator WEICKER. It is not something that I particularly cared to have buried in the course of the very important information that we heard on the AIDS funds, the cancer funds, and the infectious diseases funds that we heard about yesterday.

I can't think of any matter more critical to this Nation than that which is under your agency, and I hope I don't have to say this year after year—and I am not talking about your work, the work of your

Institute—but I can't think of anything that is being so ignored in the face of fact as the work of your Institute and the problems that will arise.

So, that being the case, I think we should put very sharp focus on it. I apologize for the inconvenience yesterday, but I will give you the opportunity now to present the matters of your concern.

Dr. WILLIAMS. Thank you very much, Senator Weicker and members of the committee. I would like to submit my written testimony and make a few brief opening comments about some aspects of it.

I am pleased to report to you at a critically important time in our Nation's Research Program as we make toward defining and understanding the aging process and the diseases and disorders of older people. We have a major challenge in the next 14 years, as the number of persons in our country over the age of 85 will more than double. Many older people are and can be healthy and fully functional, and this is one of our goals, to promote research which will lead to a full life style for all our older people. On the other hand, we face large increases in the numbers of disabled persons, and unless we can make major advances through research in preventing and treating the chronic problems and disabilities of older people, we face exponential increases in costs.

ALZHEIMER DISEASE

Among the common problems afflicting older people, Alzheimer disease and other related dementing conditions are by far the most devastating and contribute the most to burdens on families and to the costs of care. Currently these costs are estimated to be at least $38 billion per year, and they are rising rapidly.

Research on Alzheimer disease is the highest priority of the NIA and accounts for over 25 percent of our total research budget. We know much more about this disease than we did only a decade ago when the National Institute on Aging first placed research emphasis on it.

Among our epidemiologic studies in older populations we are finding that the frequency of dementia may be even higher than has previously been thought, approaching 40 percent in one study. Conversely, in some parts of the world the rate is far lower. We need much more careful and comparative epidemiologic studies in various populations before any final conclusions can be drawn.

I would like to cite a few of the recent findings from our 10 Alzheimer disease research centers and the other research grants in this field that our Institute and other institutes support. In the past year remarkable progress has been made using biochemical and molecular genetic techniques on identifying the nature of the abnormal proteins in the brains of Alzheimer victims.

The tangles inside the cells have been found to consist of a modified form of normal filaments of these cells. Investigators are now tracking back to the underlying genetic explanations for why these changes occur in what are otherwise normal filaments. Another unique protein

has been found in the amyloid plaques that occur between cells in the brain. There is some evidence that this unique protein can be detected in the serum or spinal fluid in the victim, and might serve as a diagnostic test.

There is very interesting new evidence just within the last few weeks that a major brain hormone, corticotrophin releasing factor, or CRF, is markedly decreased in certain areas of the brains of Alzheimer disease victims. At the same time, the receptors for this hormone are increased in the brain tissue. This suggests that replacement therapy—for example, with a compound like CRF—might have some value in restoring some brain functions. Work by the NIA laboratory of neurosciences in relation to this also suggests that changes in the spinal fluid concentration of CRF may serve as a diagnostic test for Alzheimer disease. So there are several clues leading toward potential early diagnostic tests. We also continue to support and emphasize the need for studies on factors affecting the family support systems for Alzheimer disease victims.

OTHER HIGH PRIORITY AREAS

Other high priority areas for research support by our Institute include the other major functional disabilities of older people, in particular, mobility problems and urinary incontinence. These are covered in my written testimony. Here I would like to state that of the more than 200,000 hip fractures that occur each year in this country now, 80 percent occur in people over the age of 85 and the cost is estimated to be at least $7 billion per year for their health care. We are encouraging and supporting more research involved in falls in older people, and are working with the new National Institute on Arthritis and Musculoskeletal and Skin Diseases to increase our collaborative support for more research on osteoporosis and osteoarthritis.

In our Baltimore Longitudinal Study of Aging we are continuing to work toward adding more women volunteers to this fundamental study. We are proceeding with the development of our new laboratory of molecular genetics.

Finally, one of my own personal goals is to increase the number of investigators and academic leaders in the fields of aging and geriatrics, fields in which there are ever-increasing requests for very scarce personnel. We have made progress in the past year in several new approaches to training and career development.

BUDGET REQUEST

Senator Weicker, the NIA considers its mission and efforts to be an investment in the future for all of us. Our fiscal 1987 budget request for this Institute is $145 million. I will be very happy to answer questions now.

Senator WEICKER. $145 million?

Dr. WILLIAMS. Yes, sir.

Senator WEICKER. What was it last year?

Dr. WILLIAMS. In fiscal year 1985, the NIA obligated $142.3 million and carried an additional $1.3 million of appropriated funds over into fiscal year 1986. The President's revised fiscal year 1986 budget is $148.3 million.

Senator WEICKER. $143 million in 1985.

Dr. WILLIAMS. That is how much we obligated. The fiscal year 1985 appropriation was $144.4 million. The fiscal year 1986 revised budget is essentially $148 million.

Senator WEICKER. That includes the 4.3-percent cut?

Dr. WILLIAMS. That includes both the 4.3-percent sequestration amount and a proposed rescission of $2.7 million. Our original appropriation for fiscal year 1986 was $157.6 million.

Senator WEICKER. The actual is $143 million?

Dr. WILLIAMS. In fiscal 1985, the NIA actually obligated $143 million.

Senator WEICKER. Then fiscal 1986 was what?

Dr. WILLIAMS. The appropriation by Congress was $157.6 million.

Senator WEICKER. And you were brought back to what, after the cut?

Dr. WILLIAMS. We were brought back by the sequestering to $150.9 million, a reduction of about $6 million. The proposed rescission drops us to $148 million, and the fiscal year 1987 proposed figure is $146 million.

LIFE EXPECTANCY

Senator WEICKER. Let me get the latest figures before I start to question you, before I just make a few comments. Let me get the latest figures in focus.

Just recently all of us saw the new statistics for average age expectancy for men and women. I believe it was around 75 for men.

Dr. WILLIAMS. That is correct, and it is almost 80 for women.

Senator WEICKER. What do you estimate the situation to be at the year 2000?

Dr. WILLIAMS. In terms of life expectancy it will, in my judgment, be up at least another 2 or 3 years for each of the sexes, although that's an estimate. We can expect to have twice as many people over the age of 85 then as we do now—over 5 million—and we will have between 38 and 40 million people over the age of 65.

Senator WEICKER. Have I heard a statistic used that relates to the year 2010? Why does that stick out in my mind?

Dr. WILLIAMS. There are a number of figures used. The year 2020 is often used because that is about when the peak effect of the aging of the so-called baby boomers will occur. By the year 2020 we will have approximately twice as many people over the age of 65 as we do now, more than 50 million.

Senator WEICKER. By 2020?

Dr. WILLIAMS. Yes, sir.

Senator WEICKER. Twice as many over 65?

Dr. WILLIAMS. Yes, sir; that's right. We will have twice as many over 85 by the year 2000. We will have twice as many over 65 by the year 2020. The latter figure, of course, includes the over 85 as well.

Senator WEICKER. The first point that I want to make, as I think it should be made, the great discussion, whenever we get into a discussion of the elderly in this country, the discussion seems to focus entirely on Social Security and the enactment of Gramm-Rudman and the fact that the problems of the elderly are taken care of because we exempted Social Security. That was it. The elderly are all fine.

I think the first thing that we had better deal with around here is the matter of perception. If, indeed, you are going to take care of Social Security and in so doing cut back on the budget of the National Institute on Aging you have not helped the elderly very much. Boy, I am going to make that point, and I don't care if I catch political heck for it.

I think Social Security is fine. It does certain things. But I tell you, as I get older, as my parents still get older, and others, I hope to heavens that there is an effort going on such as is going on at your Institute that offers the hope of some quality of life as I and they get older.

Dr. WILLIAMS. We hope so.

Senator WEICKER. Point No. 2, my staff has given me the new statistics as to how the Nation is responding to these statistics. I understand we now have 127 medical schools, certified schools, in this country. Two have full departments of geriatrics, 30 have divisions that are parts of departments, that are parts of the department of medicine or family medicine. One school has an associate dean for geriatrics.

I believe, if I am not mistaken, am I correct that my $5 million request in the last budget to start moving in this direction was thrown out of there?

Let me get some professional advice for when I come back at this problem. What would you advise me in the face of this situation in our medical schools, with clearly no great emphasis being placed in the training of physicians in this area? What would you advise me to do if you had my power in the sense to originate something that directs itself specifically to that problem?

Dr. WILLIAMS. In the first place, I see a great and rapid increase in the interest in geriatrics, in both research and education in our medical schools. In the last 2½ years I have visited close to 50 of the medical schools and a number of other teaching hospitals. Every place I go there is a clear concern about developing geriatric education and care and research programs. This includes departmental chairmen in medicine, deans, and others as well. So I am sure we are seeing a rapid movement toward far better figures than the ones you just quoted, although we obviously have a long way to go.

Second, as directed by Congress 2 years ago, our Institute led a task force of the Department that reviewed training in geriatrics and gerontology. That report was submitted to Congress in February 1984 and showed we have only about 10 percent of the estimated teachers and investigators that we need. This bears out your observation of the need. In that report we presented some options. It was not our role to specifi-

cally decide what should be done. But in terms of the options we presented, we showed that to achieve the needed nucleus of faculty in all schools, that is, to reach what we considered a full complement by the year 2000, we would need to double or triple our current training rate in terms of fellows and career programs. We had figures on all the training that our Institute, other institutes related to aging, and private sources are doing. Our figures showed that to reach those goals—if that should be considered a public policy decision—we would need to double or triple our rates of trainees and career awardees.

There are various ways to try to achieve this and I can only state possible options. These include more Federal funds in training, and more encouragement in the private sector. There are a number of foundations and private industries now that fortunately are supporting fellowship and career development training in the aging field. It is a small number, but a beginning. The NIA has instituted several approaches to take advantage of every opportunity. One of the most satisfying ones has been to add training slots onto existing research training grants in our sister institutes. For example, if there is a candidate in a Cardiology Research Training Program who would like to pursue a career of research on cardiology and aging, we are prepared to fund a trainee position added onto an existing training program to take advantage of the training capabilities already there. We did this a number of times in fiscal 1985. Thus there are ways we can try to proceed.

Senator WEICKER. In the matter of trainees, counsel points out that in last year's budget you were asking for 240, this year 195.

Dr. WILLIAMS. Yes, sir; our number of trainees is reduced.

LIFE EXPECTANCY

Senator WEICKER. I have developed the fact, Bill, that by the year 2000 we are going to have two times the number of persons over 85, and by the year 2020 again double the over 65 population.

Senator PROXMIRE. I fall into that first category.

Dr. WILLIAMS. And I also said that most older people are healthy, fortunately.

Senator WEICKER. What are the numbers we are talking about, by the way, there?

Dr. WILLIAMS. It is the expectation that by the year 2020 we will have over 50 million people over the age of 65 in our country.

Senator PROXMIRE. And they can all vote.

THE OLDER POPULATION

Senator WEICKER. They can do that, but the point that I made earlier before you came in here was those of our brethren who lead them all down the path by saying, you know, "as long as Social Security is all right, you are all right," are doing a great disservice to this population. While Social Security is exempted, we are cutting the budget of the National Institute on Aging to give them a quality of life to look forward to. It makes no darn sense at all.

I will tell you another thing that bothers me, and in discussing this problem with friends and those outside of Government, one of them turned to me—and I think this is a very popularly held belief—saying, well, actually my family doctor whom I have grown up with no longer takes any new patients, he is just going with his older patients.

I am sure however well-intentioned, that individual is probably not possessed of the most up-to-date knowledge as to what applies in this particular area. It is great to grow older together, but I think breakthroughs, whenever, came from the new generation of scientists who are doing their thing and that is transmitted to those in their various practices.

Before I turn this over to, and I am glad to have Senator Proxmire ask some questions, I again repeat—and, Jim, I turn to you as much as I do to Dr. Williams on this score—clearly the figures here are just totally inadequate to what we are facing in terms of the aging population. It is not just a question of more money. Certainly I will attend to the business of the training figures here, but in terms of getting on with this business of the medical schools, I really want some advice as to what you would like to see me do. I know I can get the support of the Congress on this score of using the medical schools, but I want to do it in a way that is going to make sense in the overall development of qualified personnel.

ALZHEIMER DISEASE CENTERS

Dr. WYNGAARDEN. The Alzheimer's centers are another development that the Aging Institute has been very active in which has created a new emphasis on dementias in aging in the medical schools. I think there is a momentum that is building.

Senator WEICKER. There is, and I was glad to be part of that. I had mixed emotions very frankly in focusing on the Alzheimer's because my own theory is that as the population gets older there are going to be other things that are cropping up here that we have to go ahead and deal with, and I think sometimes it is a mistake to focus on one aspect of problems that may very well expand into a different nature.

Senator Proxmire.

ALZHEIMER DISEASE COSTS

Senator PROXMIRE. Dr. Williams, last year's justifications state, and I quote, "The health costs for Alzheimer disease are approximately $28 billion annually." Now you place that cost at $38 billion, with $39 billion in indirect costs, for a total cost of $77 billion.

Why has your cost estimate changed so dramatically?

Dr. WILLIAMS. There are two reasons, Senator Proxmire. One is more refined analysis of available data. A very extensive indepth study has been completed by an economist on our staff this past year. Dr. Cartwright has thoroughly analyzed all available data around these cost issues and has arrived at these figures. The direct cost figure is about the same as the Alzheimer's Disease and Related Disorders Association arrived at. They estimated about $35 billion currently.

The other fact is that the number of Alzheimer victims is increasing as we get more very old people. As I pointed out earlier in my testimony, one of the latest studies just completed by our Institute in one population area shows that close to 40 percent of people over the age of 85 have significant dementia. That is almost double what we have said in the past. We have used the figure of about 20 percent over the age of 85 as——

ALZHEIMER DISEASE DIAGNOSIS

Senator PROXMIRE. Is part of the increase in Alzheimer's victims a result of better diagnosis?

Dr. WILLIAMS. Yes, sir, it is partly because of better diagnosis, but also because of more extensive surveys of total populations than we have had before.

Senator PROXMIRE. My father was a doctor. I was very close to him and used to go out on calls with him and so forth. I can't remember Alzheimer disease being a problem then. He died in 1959.

Is this a disease that has been recently defined?

Dr. WILLIAMS. Yes, sir; that is really the key, I think. Until the early 1970's it was generally thought that Alzheimer disease, as described by Dr. Alzheimer at the turn of the century, was simply a so-called presenile dementia, a disease affecting those in the age range of the fifties to early sixties. No one had really taken a careful look at the brains of people who died in their seventies and eighties with some evidence of loss of mental functioning.

The older diagnosis for such people used to be called chronic brain syndrome, which didn't mean anything very specifically, or arteriosclerotic cerebral vascular disease. The postulation was that there was poor blood flow to the brain and that is why people lost mental functioning.

But as research began to get more effective in the early and middle seventies, it was found that, in fact, well over one-half of people who die with evidence for dementia have actually the same pathological changes as Dr. Alzheimer had described in somewhat younger people. As the diagnostic efforts were further improved, it was found that many of the others had so-called multiinfarct dementia, that is, small areas of infarction or death of brain tissue.

But overall, there was no problem in blood flow to the brain. Blood flow is well maintained and our older use of the term arteriosclerotic cerebral vascular disease was simply by and large incorrect. Thus, there has been a better understanding of the process. I think probably one of the most important things to recognize over and over again is that many people do not get any dementia at all as they get older. They either have a disease process that caused dementia or their mental function is likely to be maintained very well.

ALZHEIMER DISEASE COST

Senator PROXMIRE. How much of the $39 billion in indirect costs is attributable to premature death due to dementia?

Dr. WILLIAMS. The major portion of that amount is due to premature death.

Senator PROXMIRE. Roughly how much of the total costs would be attributable to premature death? Would they be as much as one-half?

Dr. WILLIAMS. About $340 million relates to indirect costs associated with the burden of care placed on families. About $38.9 billion is associated with premature death.

Senator PROXMIRE. You have a very alarming estimate in your prepared opening statement. You say the cost of caring for people with Alzheimer disease, and I quote, "could bankrupt a Nation in the years to come if nothing is done about it."

Could you give us some cost projections to back up that statement?

Dr. WILLIAMS. Let me ask my Deputy Director, Dr. Schneider. Do you remember the projection?

Dr. SCHNEIDER. I don't have the exact figures, but, for example, it is projected that in the next century the number of individuals with Alzheimer disease in this country will be 9 million individuals, in contrast to 2 million today. So if 2 million today cost $40 billion in direct costs in today's dollars, just project it to 9 million and you have to multiply that by 4½ times.

CARE-GIVER STRESS

Senator PROXMIRE. Those costs are not in the same class with star wars, but they are very alarming.

Family members are the primary care providers for older people who require assistance in chronic situations, particularly those with Alzheimer disease. There is growing speculation that families could expand care-giving for functionally impaired relatives, thereby reducing the need for expensive institutionalization.

At the same time, there is growing concern for care-giver stress and burden. Do you have any plans for encouraging research on the family's ability to provide care?

Dr. WILLIAMS. Yes, sir; we certainly do. That is one of the priorities that we include in our support for research in aging. We have just published a summary report on review of research in the area of family support. The report identified five important areas that we are considering for further studies. These include how to understand factors that enable families to manage this problem and factors that are the greatest problem to them, the interrelation of the family and the patients. I would be very glad to provide you with a copy of this paper. It is a very specific summary of the research opportunities in this field.

Senator PROXMIRE. I would think family support would be one way we would simply have to go.

Dr. WILLIAMS. I certainly agree, sir, and I think one of the goals there should be to define the types of support that can help the families con-

tinue what they are doing, such as day programs, respite care, counseling, and financial help. There are a number of options.

Senator PROXMIRE. Let me ask you about another aspect of the same issue. This is my last question. On page 213 of your justifications, the following statement is made, and I quote: "NIA-supported research is demonstrating that families can learn strategies to cope with behavioral problems of elderly relatives that might otherwise lead to premature institutionalization."

That is the subject we were discussing before, but can you tell us what your strategies are and tell us how successful that approach has been?

Dr. WILLIAMS. What we have learned is that families' participation in support groups, as has been promoted to a great extent by the Alzheimer's Disease and Related Disorders Association, has been effective in helping family members cope with the stress that come with this problem.

We also have evidence of the value of respite opportunities for families and of counseling roles. An area that is being explored, that we have not had a direct involvement in, is some ways to help families carry the financial burden through some type of financial offsets for them.

Senator PROXMIRE. That's so critical. How much do you plan to spend on that kind of strategy in 1986 and 1987?

Dr. WILLIAMS. Do we have figures that would show that specifically on the type of Alzheimer family support work?

Ms. ROSS. No; we don't.

Dr. WILLIAMS. I don't think we have a specific figure. I can provide it, I don't think I have it right here.

Senator PROXMIRE. We'd appreciate it if you could provide that information.

[The information follows:]

We are currently providing approximately $1 million for research on family support systems.

PREPARED STATEMENT AND QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Thank you very much, Senator Proxmire. I have further questions for response to the record, Dr. Williams, and there will be other questions from other members of the panel.

I would expect as is the case with most of the institutes again my staff will be working with you in the next week or so to develop some more figures that might be more in line with the committee's thinking. Thank you very much.

Dr. WILLIAMS. Thank you.

[The information follows:]

Statement of Dr. T. Franklin Williams

I am pleased to report to you today at a critically important time in our nation's research program aimed at defining and understanding the aging process, the medical and social imperatives of this century. In the next 14 years, the number of persons in our country over age 85 will more than double. Many older people are and can be healthy and fully functional, but unless and until we can make major advances in our prevention and treatment of the chronic problems that are common in older people, we face large increases in number of disabled persons—and exponential increases in costs.

To understand aging, scientists must examine an immensely broad range of topics. Molecular biology, immunology, pharmacology, neurology, psychology, social and behavioral sciences, epidemiology, and genetics are but a few of the disciplines that must be part of any comprehensive study of aging.

The ultimate goal of all research on aging is to reduce the impact of age-related disabilities and diseases, thereby improving the quality of life in the later years. This goal does not mean, however, that only those individuals 65 and older will be affected by the results of aging research. To bring about significant improvements in the health of future generations, people of all ages will need to make changes in lifestyle, diet, and personal health care practices. Studies conducted and supported by the NIA will help define these lifestyle changes.

Research on Alzheimer disease, the most common form of dementia among the elderly, continues to be a high priority for the NIA. We know many things about Alzheimer disease that we didn't know a decade ago. More physicians know it when they see it; they even know how to treat some of its less serious symptoms, but they don't know how to stop it from getting worse or how to cure it. Scientists know more about what goes on inside the brains and bodies of people who have it, but they still don't know what causes it. Policymakers know that more people have it, and that the cost of their care could bankrupt a nation in the years to come if nothing is done about it. And the general public knows it exists...which is more than they knew a decade ago.

By most estimates, Alzheimer disease is the cause of serious confusion and forgetfulness in some 2.5 million American adults. This is five times the estimate that appeared in the literature 10 years ago when the NIA began its first studies in this area. But these latest estimates stand for more than just growing numbers of older people. They reflect, in addition, a more sophisticated, if not yet perfected, approach to diagnosis; better training of health care professionals regarding the problems of old age; and a greater awareness of Alzheimer disease and its symptoms among the general public.

In fact, according to experts at Harvard University, our current estimates of the number of Alzheimer victims may still be too conservative. In one of the four NIA supported Established Populations for Epidemiologic Studies of the Elderly, the Boston group has found that more than 10 percent of the study population over age 65 may be suffering from some sort of dementia. This is double the frequently

stated estimate of 5 percent. The numbers reach almost 40 percent among those aged 85 and older.

According to the Alzheimer's Disease and Related Disorders Association, $35 billion was spent last year on the care of Alzheimer patients. This includes the costs of nursing home and other long-term medical care, but doesn't begin to account for the emotional and social costs of the disease. In a soon-to-be-published paper, NIA health economist Dr. William Cartwright and colleagues at Howard University and Pennsylvania State University have tallied some of the specific costs of Alzheimer disease, suggesting that $35 billion is just the tip of the iceberg, and speculate that the special services required by dementia victims might cost more than $38 billion, with another $39 billion for indirect costs to the families involved, with a total, minimum, cost of $77 billion.

The NIA supports major research activities on Alzheimer disease and related dementias in older people, including 10 Alzheimer Disease Research Centers. These centers have begun to produce important scientific knowledge. At one of the centers, it has been found that nuclear magnetic resonance (NMR) imaging can detect very early signs of small strokes or multi-infarct dementia and distinguish them from Alzheimer disease. This will enable physicians to institute appropriate treatments, thus preventing further deterioration. Research at other centers is defining the genetic component of Alzheimer disease.

One of the characteristics of Alzheimer disease is the presence of amyloid fiber deposits in the brain's blood vessels. An NIA supported scientist has isolated and analyzed these amyloid fibers of Alzheimer patients and found a unique protein not seen in healthy individuals. Interestingly, the same protein appears in the amyloid deposits of Down syndrome, representing another link between Alzheimer and Down syndrome. Future plans call for the use of monoclonal antibodies to take a closer look at this unique protein with the hope of isolating its precursor. This work reveals yet another clue that Alzheimer disease is a systemic disorder, and may lead to a simple diagnostic test for the disease.

Since the late 1960's, some scientists have speculated that Alzheimer disease might result from a so-called "slow virus" infection, caused by an infectious agent that hides within the body for years before producing devastating disease. In this area, too, our questions have become more sophisticated, with scientists looking at the fundamental processes involved in the development of the virus. Previous studies have identified the infectious "prion" protein associated with some slow-virus disorders. More recently it has been demonstrated that the prion is part of a larger protein present in both normal and infected cells. In normal cells, the larger protein is completely broken down by enzymes; in infected cells, the defective breakdown leaves the prion intact. This prion has a fibrous structure that resembles certain filaments found in the brains of Alzheimer patients.

The primary goal of geriatric research and treatment is to maintain effective functioning and independence in living for older people, to the maximum extent possible, in the face of chronic diseases and disabilities. The extent to which we can improve our

capabilities to address such problems successfully will largely determine what the burden of care is going to be for individuals, families and society, as the number of old and very old people rapidly increases. A number of disorders and diseases that afflict older people and result in disability and institutionalization have received too little attention from the medical research community. These include such major functional disabilities as urinary incontinence and problems of mobility with the frequently associated complications of falls and hip fractures. The NIA is developing programs to address these conditions specifically.

Urinary incontinence is a common disorder that affects not only many institutionalized patients, but many community-dwelling men and women as well. Estimates indicate that about half of all nursing home residents and 7 to 14 percent of noninstitutionalized older adults are incontinent of urine.

Intramural scientists at the NIA's Gerontology Research Center (GRC) in Baltimore, Maryland, have just published their very encouraging results of a study of the therapeutic effectiveness of a combination of physical therapies and behavioral training procedures in elderly women affected by either stress incontinence, bladder hyperreflexia, or urge incontinence. They have documented a major reduction or elimination of incontinent episodes in 80 percent of the patients.

Such accomplishments, if they can be achieved more generally, could help considerably to reduce the costs of care for persons with this problem -- a cost that is estimated to be at least $1.5 billion for patients in nursing homes alone. Five clinical trials of treatment of urinary incontinence are now in progress at academic centers around the country, jointly funded by NIA and the Division of Nursing Research, HRSA. The Baltimore research team, with partial support from the Health Care Financing Administration, is extending its studies in nursing home patients.

Hip fractures are both more common and more serious in older persons. They are a leading cause of disability in older adults and account for a high percentage of nursing home admissions. Of the more than 200,000 hip fractures each year in the United States, 84 percent occur in persons over age 65 years. One year after a hip fracture, 20 percent of the surviving victims cannot walk. In addition to their direct impact on health and independence, hip fractures have been estimated to cost over $7 billion in 1984 and are certainly higher today. A major area of research interest related to fractures is osteoporosis.

Osteoporosis is a degenerative bone disease affecting as many as 20 million Americans, most of them over 50 years of age. The disease results in brittle, fragile bones, and thus is directly related to fractures. It is estimated that over 90 percent of women have significant osteoporosis by age 85. This problem, little recognized in the past, is like Alzheimer disease, a new silent epidemic. Research findings indicate that this disease may have multiple causes. The NIA is collaborating with the new National Institute of Arthritis and Musculoskeletal Diseases to considerably increase research on the causes and potential treatments for osteoporosis as well as for osteoarthritis, another major cause of loss of mobility in older people. There are promising opportunities for comparative

studies with other nations and cultures where osteoporosis, osteoarthritis and Alzheimer disease may be less prevalent than in the United States.

With increasing longevity and growth in absolute numbers of older people, the need for improved health and functioning will become overwhelming before the end of the century. There is a pressing need to discover the mechanisms by which age-related declines may be prevented, reversed or ameliorated. Research supported by the NIA suggests that the productivity of the middle years can be extended and that many disabilities of old age can be prevented, reversed, or postponed, thus improving the quality of life for older people and containing the costs of health care and dependency.

Aspects of lifestyle, in particular nutrition and exercise, are thus commanding a great deal of research attention. At the NIA, research on nutrition is attempting to define the nutritional requirements for good health in the elderly; to determine how dietary deficiencies are associated with depressed immuno-competence, depressed cognitive function, or overt metabolic disease; and to determine how eating behaviors change with aging. Research on exercise physiology examines how physiologic (e.g., pulmonary, cardiovascular, or neuromuscular) adaptation to exercise is altered by aging, and whether regular long-term physical activity can help prevent such age-related disorders as hypertension, maturity onset diabetes mellitus, and osteoporosis.

Special opportunities for deeper understanding of the aging process which currently exist need to be capitalized upon. Techniques are available to probe genetic changes, to distinguish aging processes from disease, and to specify the social conditions influencing the ways people grow old. New methods, data, and concepts are becoming available for forecasting life expectancy as well as active life expectancy. The Baltimore Longitudinal Study of Aging, with its highly characterized population of healthy volunteers, wealth of longitudinal date, and multidisciplinary and multivariate approach, is a unique resource to study human aging. Increased knowledge of how biological, psychological, and social aging processes interact to produce particular strengths and weaknesses in older people will be used to identify appropriate mechanisms for preventing diseases and disabilities and enhancing health and independence.

Recombinant DNA technology, a powerful tool for exploration of gene structure and function, has yielded remarkable information about a large variety of genes. Investigators interested in the biology of aging are now employing this technique in the study of genes related to aging processes. Examples of planned and on-going research include identification and characterization of genes preferentially expressed during senescence; analysis of restriction fragment length polymorphisms to identify fragments of human DNA carrying defective genes (e.g., the gene for familial Alzheimer disease); and examination of the relationship between age and transcription of specific DNA sequences.

The population aged 85 and over has been growing at over three times the rate of the population aged 65 and over, while the population aged 95 and over has been growing at twice the rate of the

85 and over age segment. Members of this age group have very high rates of morbidity and disability and are heavy users of care. Almost 25 percent are institutionalized, and 40 to 45 percent of non-instutionalized people need the help of another person in everyday life. Less is known about this age group than about any other. It is now feasible to develop realistic projections of the future size and composition of the Nation's 85 plus population, including future patterns of mortality, morbidity, disability, and need for care. By enhancing Federal databases, gaps in Federal and international statistics on the oldest old can be filled, thus enhancing our ability to study the special problems and needs of this cohort.

Mr. Chairman, the 1987 budget request for this Institute is $145,829,000. I will be happy to answer any questions.

Biography of Dr. T. Franklin Williams

Birthdate: November 26, 1921 - Belmont, North Carolina

Education: B.S., University of North Carolina, 1942; M.A., Columbia University, 1943; M.D., (Cum Laude) Harvard Medical School, 1950

Professional History: 1983 to present, Director, National Institute on Aging, NIH; 1983, J. Lowell Orbison Alumni Distinguished Service Professor; 1982-1983, Director of the Geriatric Unit, Monroe Community Hospital, Rochester, N.Y.; 1980-1983, Co-Director, Center on Aging, University of Rochester Medical Center; 1968-present, Professor of Medicine and of Preventive, Family and Rehabilitation Medicine, University of Rochester; 1968-1982, Professor of Radiation Biology and Biophysics, University of Rochester; 1968-1982, Medical Director, Monroe Community Hospital, Rochester, N.Y.; 1977, L.S. McLeod Visiting Professor of Geriatric Medicine, University of Adelaide and South Australia Postgraduate Medical Education Association; 1956-1968, Instructor to Professor of Medicine and of Preventive Medicine, University of North Carolina; 1954-1956, Fellow in Medicine, University of North Carolina; 1953-1954, Assistant in Medicine, Boston University; 1953-1954, Senior Resident Physician, Boston Veterans Administration Hospital; 1950-1953, Intern and Assistant Resident Physician, John Hopkins Hospital; 1942-1943, Assistant in Chemistry, Columbia University.

Military Service: 1983 to present, Assistant Surgeon General, U.S. Public Health Service; 1943-1946, Communications Officer, U.S. Naval Reserve, active duty.

Societies and Associations: American Association for the Advancement of Science (Fellow); American College of Physicians (Fellow); American Federation for Clinical Research; American Public Health Association (Fellow); American Society of Human Genetics; American Geriatrics Society; American Diabetes Association; Society for Experimental Biology and Medicine Rochester Academy of Medicine; New York and Monroe County Medical Societies; Gerontological Society of America; New York State Public Health Association; Institute of Medicine, National Academy of Sciences; The Royal Society of Medicine; and Academia Medicorum Litteratorum.

Honors and Awards: Phi Beta Kappa; Alpha Omega Alpha; Sigma Xi; Member, Institute of Medicine; Diplomate, American Board of Internal Medicine; Diplomate, National Board of Medical Examiners; Markle Scholar in the Medical Sciences; Special Fellow, Department of Physiology, Vanderbilt University; and Honorary Member, American Academy of Orthopedic Surgeons.

Publications: Author of over 112 scientific papers and abstracts.

Questions Submitted by the Subcommittee

TRAINING

Question. Dr. Williams -- you and I have expressed our concern about having sufficient numbers of researchers and health professionals trained in geriatrics and gerontology. The Association of American Medical Colleges informs me that out of the 127 American medical schools, only 32 have either a division or department for geriatric medicine. What has the National Institute on Aging been able to accomplish in this area?

Answer. The 1984 congressionally mandated Report of the Health and Human Services Taskforce on "Education and Training in Geriatrics and Gerontology" calls for a doubling to tripling of the yearly numbers of postdoctoral fellows and trainees in order to reach minimally adequate numbers of faculty in the Nation's medical and other health professional schools by the year 2000. In response to this need, NIA designed the following new mechanisms to be used in addition to existing mechanisms for support of training:

The Geriatric Leadership Academic Award (K07) to develop leadership and research and training activities in geriatrics at health centers and other health professional schools by supporting midlevel or senior faculty as academic leaders and program coordinators. The first two such awards were funded by NIA in FY 1985.

The Complementary Training Award for Research on Aging (T32) permits strong, well-established research training programs in scientific fields relevant to aging to extend their efforts to the preparation of individuals who are interested in careers in aging-related research. To date, NIA has funded one of these awards.

The Co-Funded Institutional National Research Service Award (T32) supports aging-related training positions on institutional training grants awarded by other NIH Institutes in areas relevant to aging research issues. NIA filled 15 of these positions in FY 1985.

In addition, the Institute is currently distributing 500 new folders describing seventeen support mechanisms awarded by the NIA and other NIH components, as well as 2,000 announcements about the availability of the new folders, "Training Opportunities in Geriatrics and Gerontology."

Also, a summer Institute in Geriatrics is being planned in association with the American Geriatrics Society and Boston

University. This is a pilot program sponsored by NIA for fourth-year medical students interested in geriatrics. It will provide exposure to established academic role models and will acquaint students with the challenge and need for professional careers in the field.

Research training opportunities are also included in the NIA Teaching Nursing Home Program and the Alzheimer Disease Research Centers (and are being planned for the Alzheimer Disease Registry Center).

The NIA expects to continue to take the lead among the Federal agencies concerned with training in geriatrics and gerontology by developing, in cooperation with the HHS Task Force, a report on Personnel to meet the Health Needs of the Elderly as required by the Health Research Extension Act of 1985.

Question. How does this compare with the needs outlined in your report on education and training in geriatrics and gerontology?

Answer. The number of competing NIA extramural Research Career and National Research Service Award training positions rose from 49 in FY 1980 to 100 in FY 1985. In FY 1986, NIA expects to fund 42 competing extramural trainees. The President's FY 1987 Budget provides for 47 competing extramural trainees. At the reduced rate, Objective Five of the HHS Report on Education and Training in Geriatrics and Gerontology, calling for at least 600 investigators -- other than physicians -- to be prepared by 1990, and 1,300 by 2000, will not be met.

Within the NIA Intramural Research Program, opportunities exist for medical and intramural staff fellows to receive training in the NIA laboratories, most of which are located at the Gerontology Research Center in Baltimore. The number of new fellows increased from 8 in FY 1980 to 22 in FY 1983. Six fellows received training in 1985. There are no prospects to increase this number beyond the FY 1985 level.

Question. How much funding would be necessary in FY 1987 to achieve your training goals?

Answer. An additional $2.7 million would support 79 more new intramural and extramural trainees, bringing the number of new trainees supported in FY 1987 to a total of 132. Of this amount, $1.1 million would be for research career awards and $1.4 million for individual fellowships and institutional awards. Another $200,000 would support additional intramural staff fellows.

REDUCING HEALTH CARE COSTS

Question. The Health Care Financing Administration reports that the cost of health care in this country is rapidly approaching the $400 billion level. About 30% of this amount, or $120 billion, is believed to pay for the care of the elderly. What kind of research opportunities are you supporting that could have a direct impact on reducing that cost?

Answer. A large portion of these costs relate to Alzheimer disease (AD). The search for a way to prevent AD remains our number one priority. The human and financial costs of AD are well known.

NIA extramural research seeks the causes of AD, as well as means of prevention, diagnosis, and treatment. Studies by the NIA Laboratory of Neurosciences (LNS) are designed to aid in the differential diagnosis of primary progressive dementias and to establish parameters against which therapeutic regimens can be developed and evaluated.

Hip fractures, a major cause of death and disability among the elderly, are directly related to the loss of bone strength caused by osteoporosis and to the increased likelihood of falling among the elderly. Of the approximately 200,000 hip fractures in this country each year, about 84 percent occur in people 65 years of age and older. The annual costs associated with hip fractures in the U.S. were estimated at more than $7 billion dollars in 1984, and are certainly higher today.

Although falls and gait disorders are extremely important public health problems, little research attention has been concentrated on those areas. To address this gap, the NIA issued an initiative for research on the neurologic, cardiovascular, muscular and perceptual factors underlying falls and gait disorders in older people. This major effort is aimed at understanding the specific diseases and conditions that result in falling, and at pointing us to the development of interventions to prevent falls. Additionally, the NIA, in collaboration with the National Institute of Arthritis and Musculaskeletal and Skin Diseases (NIAMS), has developed an initiative for research on osteoporosis: Programs of Excellence of Research on Osteoporosis. The long range goal is to understand the causes of osteoporosis, to identify who is at risk of developing osteoporosis, to recommend individually tailored and tested prevention strategies, and to provide tested strategies for retarding the rate of progress of the condition and for restoration of diseased bone. These advances in the prevention and treatment of osteoporosis and subsequent reduction in fractures would result in substantial economic savings.

Research on systolic hypertension, strokes, and multi-infarct dementia also has great potential for reducing medical costs for the elderly. Isolated systolic hypertension (ISH) is responsible for as many as 90,000 major strokes per year. The direct costs of these strokes are at least $1 billion dollars. In addition to causing major strokes which cause death or paralysis, ISH is a cause of repeated small strokes which often lead to dementia. The frequency of dementia due to small strokes (multi-infarct dementia) is estimated at 30 to 50 percent of all dementia cases. Dementia accounts for 58 percent of nursing home admissions and imposes other costly burdens on families. The annual costs to the Nation of multi-infarct dementia currently are estimated at $12-$20 billion dollars.

The Systolic Hypertension in the Elderly Program (SHEP), equally sponsored by NIA and NHLBI, will determine the benefits of treating Isolated Systolic Hypertension (ISH), a form of hypertension almost uniquely confined to persons over 60 years of age. While the risk of ISH is well established, the SHEP trial is necessary to determine whether or not it is reversible. If results of this trial demonstrate that stroke and multi-infarct dementia can be prevented by treatment of ISH, this will mark the first major impact on the

problem of dementia in the elderly, with potential savings of many billions of dollars each year.

The NIA also has a major initiative on health and effective functioning in the middle and later years. The initiative calls for research that can specify how the relatively vigorous health, effective functioning, and productivity of the middle years can be continued into the later years and how many of the disabilities of old age can be prevented, reversed or postponed. Research in this area can contribute directly to reducing the need for expensive health care.

The NIA intramural program supports numerous efforts with the potential to have a direct impact on the cost of health care. For example, estimated costs for urinary incontinence are approximately $2 million per year. Intramural scientists have developed behavioral interventions to treat incontinence in geriatric patients. The studies reflect many years of investigation and exemplify how health care advances are critically dependent upon continuing support of basic research. A collaborative inpatient program has now begun to assess the utility of these treatment modalities in a patient population typical of nursing home residents. In view of the significance of the problem of incontinence and the potential for substantial savings in health care costs, the Surgeon General has lent his active support to this collaborative effort. The Health Care Financing Administration is defraying a major portion of the clinical costs of the three year study.

The Baltimore Longitudinal Study of Aging (BLSA) seeks (1) to describe age differences and age changes in an array of variables (e.g., body composition including lean body mass), organs, and systems; (2) to determine the mechanisms underlying the age effects identified; (3) to assess the impact of those age effects on other variables, on disease development, and on morality; and (4) to define normative standards as influenced by age. Such standards -- age-specific weight-for-height tables and age-adjusted standards for performance on the cortisone glucose tolerance test used clinically to diagnose diabetes -- have immediate health care implications and, consequently, favorable cost impacts.

BUDGETARY RESTRAINTS

Question. What sorts of things do you think you should be doing which you cannot do because of current budgetary restraints?

Answer. A number of meritorious Alzheimer disease research project grant applications are currently not being funded. In addition, the Alzheimer Disease Research Centers (ADRCs) will be supported below recommended funding levels in both FY 1986 and FY 1987. Examples of ADRC projects which will be delayed include a project to determine whether there are subgroups of patients within the classification of AD; a project to study the chemistry of neurofibrillary tangles, the primary brain pathology in AD; and a project to isolate a specific and unique DNA fragment from the genome of patients identified as manifesting familial AD.

The intramural Laboratory of Neurosciences (LNS) is using a combination of sophisticated new techniques to examine fundamental brain processes in three populations: healthy subjects of different

ages; Alzheimer disease; and Down syndrome. At the proposed budget, the pace of the research will be slowed.

NIA efforts in the areas of falls and osteoporosis are limited by the current budgetary restraints. The NIA anticipates funding approximately 6 to 8 investigations on falls for a total cost of $1.25 million in FY 1986. Establishment of an adequate core of investigations on falls would require an additional 6 to 8 studies in FY 1987. Because of budget constraints, we will only be able to allocate $2.25 million to support Programs of Excellence of Research on Osteoporosis. This will be enough to support programs at two centers in FY 1987 where we believe at least 6 are needed. A total of $1.5 million dollars have been allocated jointly by NIA and NHLBI for research on the mechanisms responsible for age-related increase in blood pressure. However, we believe that at least $3 million dollars per year would more adequately fund research in this field.

An empirical model of elderly health expenditures has been proposed for development in the second year of an on-going study on the dynamics of health expenditures in the older population. This model would use data available from cross-sectional surveys such as the National Medical Care Expenditure survey, National Medical Care Utilization and Expenditure survey. It would be used to address the implications of health changes and policy changes on older people. Under the present budget, this project will not be activated.

In the area of health and effective functioning, we will be unable to fund additional studies on the oldest old. We are prepared to support more work on technology transfer and human factors studies of aging. Research on hearing and aging, an area of widespread concern, also needs to be developed. Identification of behavioral risks factors in the older population should be pursued by research as should work on gender differences in health and longevity and research focusing on intergenerational relations and family caregiving. Increased knowledge in all these areas could lead to decreased health care costs.

The new intramural Laboratory of Molecular Genetics has been forced to cut its projected staffing. Molecular genetics is an area of high priority since it will lead to increased understanding of aging and age-related diseases.

Budget restraints have precluded participation by NIA intramural scientists in a collaborative venture to study immune responses of elderly individuals to different types of influenza vaccines. Influenza is the fourth leading cause of death among older individuals yet many vaccines are not efficacious for them. By using vaccines that elicit humoral, cellular and/or mucosal immune response in in vivo situations the extent and type of age related immunodeficiency could be determined. The collaborators will proceed with the study in children; however that segment which would have outlined the efficacy of different vaccine types for older people will not be pursued in light of the NIA withdrawal.

It has been estimated that the cost of health care for age-related bone disorders approximates $5 billion per year. Yet little is known about the mechanism of loss in bone mineral with age. Intramural scientists have conceived a new initiative which could begin to fill this knowledge gap. This proposal is a major program

expansion to investigate the pathophysical bases of bone loss with the goal to delay or prevent the loss of bone with age. These new studies would focus on the development of bone and other cell types as experimental models to examine how hormones, including estrogens, parathyroid hormone, vitamin D metabolites, calcitonin and glucocorticoids, act to regulate mineral deposition and loss. A modest beginning has been made in that both animal model and human bone cell lines have been started. More could be done.

HEALTH PROBLEMS OF THE ELDERLY

Question. Some of the chronic health problems of the elderly include: high blood pressure, incontinence, problems with gait and balance, and osteoarthritis. What research is being done in these areas, and is it enough?

Answer. NIA's major support for extramural research on high blood pressure in the older population is devoted to the Systolic Hypertension in the Elderly Project (SHEP), which it supports equally with NHLBI. SHEP is a clinical trial to determine whether drug treatment of systolic hypertension is effective in reducing the number of strokes and deaths. While support for the SHEP trial is adequate, there is insufficient support for research on the causes of the rise in blood pressure with increasing age, which is responsible for most of the systolic hypertension in older people. If we could learn the causes of this rise in blood pressure with age, we might be able to develop ways to prevent systolic hypertension that are safer and less costly than drug treatment.

The NIA is also supporting intramural research on high blood pressure. NIA intramural scientists are studying the application of behavioral techniques to the control of high blood pressure. Results obtained to date suggest that it is possible to reduce medication for many patients. A follow-on clinical study is planned to evaluate the effectiveness of a behavioral stepped care treatment procedure in controlling blood pressure of older patients with isolated systolic hypertension.

A major focus of the NIA Laboratory of Cardiovascular Science is to develop new information about the effect of age on cardiac structure and function. In keeping with this objective, an international study is planned to measure vascular stiffness and left ventricular wall thickness and filling properties in a large number of individuals in two populations of the People's Republic of China: one that exhibits an age-related increase in blood pressure with age; and one in which this increase does not occur or is retarded. The proposed study is designed to answer whether specific age-related heart changes which occur within our "normal" range are in fact "normal" or whether they are absent in a population in which blood pressure does not increase with age.

The NIA is supporting a number of extramural studies on urinary incontinence. These include studies of the neural control of the urinary bladder, pharmacologic and behavioral treatments of incontinence in women, the epidemiology and clinical diagnosis of incontinence in a defined population, and the treatment and management of incontinence in nursing home and long-term-care facilities. A major epidemiological study of incontinence in community residing older people has found that the prevalence of

incontinence is quite high with 18.9 percent of men and 37.7 percent of women experiencing one or more episodes of involuntary urine loss in the prior 12 months. A study in nursing home patients revealed a previously unrecognized syndrome responsible for incontinence in almost one-third of the patients.

The long-range goal of the NIA's extramural Genitourinary Disorders Program is to support research which will lead to the development of algorithms for the fewest and least invasive diagnostic procedures possible for patients with urinary incontinence and for the systematic application of treatment techniques (surgical, pharamacologic, behavioral or combinations). Additional research is clearly needed to reach this goal.

The NIA intramural program, through its Laboratory of Behavioral Sciences, has made a major intellectual and scientific investment in studies of incontinence. Intramural scientists have developed behavioral interventions to treat fecal and urinary incontinence in geriatric patients. Research is now being conducted to further validate, apply and extend these techniques on both an outpatient basis and in an inpatient setting. One project completed this year, which is one of a comprehensive series of studies on behavioral treatment methods for incontinent, community-dwelling persons, showed that the feedback of bladder and sphincter activity greatly enhanced the effectiveness of the Kegel exercise treatment of urinary incontinence. In view of the success rates achieved in reestablishing continence on an outpatient basis, an inpatient program has now begun to assess the utility of these treatment modalities in a patient population typical of nursing home residents.

The NIA is presently supporting only a few studies of gait and balance problems in older people. One investigation is determining the frequency and characteristics of falls in nursing home patients. A second investigation is isolating specific neuromuscular deficits in people who fall. Because of the importance of the problem and the virtual lack of research, the NIA issued a Request for Applications for studies of the neurologic, cardiovascular, muscular and perceptual aspects of falls and gait disorders. However, this initiative will not result in an adequate core of investigations.

The recently created intramural Applied Physiology Section has targeted studies on gait as an area to be pursued if resources permit. The present nomenclature and categorization of gait disturbances is inadequate. Modern techniques of video recording and computer interpretation of gait could be extended to the healthy aged as represented by the Baltimore Longitudinal Study of Aging and that portion of the population broadly classified with "gait disturbances". A more discrete definition of the problem is a prerequisite to studies of etiology and intervention.

Osteoarthritis is another very common debilitating disorder of older people. Currently the NIA is supporting five investigations which are primarily basic science investigations of the function and biochemistry of cartilage. In cooperation with the National Institute of Arthritis and Musculoskeletal and Skin Disorders (NIAMS), has considered issuing a program announcement or a Request for Applications in FY 1987 to stimulate this under-researched area.

Question. In your professional judgment, how much in the way of additional funds do you think could be used effectively in these areas of research?

Answer: An additional $10.0 million would provide a much needed impetus to Alzheimer disease research. $1.5 million more per year is needed for an adequate extramural program on high blood pressure in the older population. For research on falls, gait and balance, an additional $1.25 million per year is needed. For additional research on osteoarthritis, it is our estimate that an additional $750,000 per year is required. Total additional funds for intramural research -- including molecular genetics, neurosciences, and blood pressure studies -- are estimated at $3.4 million.

MINORITY AGING

Question. Due to lifelong economic problems facing our minority populations, I would expect that they may present a different health profile when they become senior citizens. Is this true, and if so, can you identify for us what these problems are?

Answer. It is well known that distributions of risk factors and of certain diseases differ among U.S. elderly of Spanish heritage, black elderly, and white elderly. For example, data from the Ten State Nutrition Survey, 1968-1970, reported that overall the diets of older blacks seemed to be characteristically low in content of iron, thiamine, and calcium while those of Spanish Americans seemed to be low in vitamin A content. Similar proportions of white and black men are obese, but black women are more likely to be obese than white women. Smoking is more prevalent among blacks than among whites. At every age -- except at very young ages -- blood pressure for blacks is greater than that for whites. Hypertensive heart disease is much more prevalent in blacks compared to whites.

Numerous studies have shown that blood pressure is higher in blacks than in whites at all ages. However, in lower socioeconomic groups in all races blood pressure is higher. Systolic blood pressure rises more steeply in older blacks than in older whites. Evidence indicates that hypertension in blacks is more closely associated with salt intake, and less closely related to endocrine factors than in whites. The same studies show that older blacks with hypertension respond better to diuretic therapy and less well to certain other types of antihypertension medication than whites.

Type II diabetes is more prevalent among minorities than in the white population. In Blacks and Hispanics, the prevalence rate is about three times that in whites. Among Native Americans, one group, the Pima Indians, have a 50% rate of diabetes. Obesity is also highly associated with diabetes, especially among Black females and Native Americans. Because of this high association, it has been estimated that control of obesity could prevent almost 300,000 cases of diabetes a year -- a reduction of approximately 50%.

Both the black and hispanic elderly populations demonstrate an interesting phenomenon known as "mortality cross-over". Mortality rates are higher for these populations at younger ages, presumably because of lifestyle and socioeconomic risk factors. However, at older ages black and hispanic mortality rates become lower than those

of whites. While there is a debate about exactly how much of this "cross-over" is due to poor age-reporting data and how much is due to adverse selection resulting from differences in risk factor profiles, it is highly likely that economic problems, along with other social factors, play an important role. In short, little is known about the health and functioning profiles of minority elderly, let alone about potential causal factors. However, data suggest a generally higher prevalence of disability.

Question. What research are you currently supporting that addresses these problems?

Answer. The NIA Director was a member of the recent Task Force on Black and Minority Health. This Task Force identified six causes of death that together account for more than 80% of the mortality observed among Blacks and other minority groups in excess of that in White populations. Of the six causes of death -- cancer, cardiovascular disease and stroke, chemical dependency, diabetes, homicide and accidents, and infant mortality -- three are diseases that increase in prevalence with age. The lack of health-related information on people over age 70 by ethnicity became very obvious in reviewing existing data. The NIA is now supporting activities in collaboration with the National Center for Health Statistics to deal with this deficiency, and is also initiating research on aging within minority groups. An important new mechanism to support preliminary studies and planning for major research on biomedical and behavioral aspects of aging in minorities is now under development.

In 1984 the National Institute on Aging awarded a competitive contract to Duke University to establish a population to study black elderly. This population will be followed for five years through two household interviews and telephone callbacks to collect information on risk factors for disease, measure of health status, and prevalence and incidence of disease. Risk factors measured will include data on widowhood, retirement, bereavement, social networks, socioeconomic status, alcohol and smoking patterns, prescription and non-prescription drug use, physical activity, and sleep patterns. Measures of health status will include reported chronic health conditions, mortality, disability, hospitalization, and admission to nursing homes. In addition, data on elevated blood glucose, dementia, diet and hypertension, sickle cell trait, and renal disease will be collected on samples of the population selected for study.

The Systolic Hypertension in the Elderly Program (SHEP), cofunded with the National Heart, Lung, and Blood Institute (NHLBI), is designed to study the benefits of treatment in 5,000 persons aged 60 and over. It includes cohorts of minority Americans. The study is designed in such a way that the results of treatment can be analyzed separately in different age, sex, and race groups.

Via an interagency agreement between NIA and the National Center for Health Statistics, the Longitudinal Study on Aging (LSOA) is reinterviewing all minorities over age 70 who took the 1984 Supplement on Aging to the National Health Interview Survey. Although the sample is small, the study should provide some evidence about the transitions between independent and dependent functioning that are associated with initial economic status.

In addition to the LSOA, NIA has supported several grant projects on minority populations and aging covering such topics as disability and coping among older black women, demography of the extreme aged, informal support networks of the black elderly, psychosocial links to hearing handicap in black elderly, and a major study of black households, life satisfaction and social supports.

Question. What more should be done and at what cost?

Answer. Given the high rates of morbidity and the expected changes in the nature of minority cohorts entering old age, more research needs to be done in areas such as paths to poverty, health consequences of economic impoverishment, psychosocial risk factors for hypertension, and differential risk factors within the black population. There is a strong need for the establishment of special research centers and training programs in the demography and epidemiology of minority health. Initiation of such projects would require approximately $300,000.

A Request for Applications on Mechanisms of Age-Related Increase in Systolic Blood Pressure has been issued jointly by NIA and NHLBI. It has specifically solicited research that will help to understand racial differences in blood pressure change with age. A total of $1.5 million per year has been allocated for this research by the two Institutes. A level of $3 million per year would move this work along at a faster pace.

Because of the large component of Hispanic elderly in the U.S., it would be important to establish a population for study of Hispanic elderly. The cost for this project would be approximately $800,000 per year for 6 years.

ALZHEIMER DISEASE RESEARCH

Question. Please bring us up to date on the research findings concerning Alzheimer disease. Have there been any promising lines of inquiry since last year?

Answer. The role of genetic factors in contributing to the development of Alzheimer disease continues to be a very important and promising area of research. Several of the 10 Alzheimer Disease Research Centers, and also other laboratories, are addressing this challenge. In the ADRC at University of California, San Diego, Dr. Gary W. Small and collaborators have found an increased association of AD in young onset victims with one specific HLA antigen (one of the family of cellular antigens which can be tested for in samples of blood and are used, for example, in matching organs with potential transplant recipients). In a somewhat similar approach, Dr. Gerard Schellenberg and collaborators at the University of Washington ADRC have found an increased association of AD in families with the dominant form of inheritence of AD, with one of the genotypes of an apolipoprotein, a protein in the circulating blood. While these are only "associations" at this point, they give leads to which chromozones may be involved in transmitting the risk for acquiring AD. With a major coordinated effort among a number of scientists who are now involved in gene-mapping, it seems quite possible that we could proceed within a relatively short time, perhaps 3 or 4 years,

to identify the genetic area responsible for the genetically transmitted form of this disease.

Dr. Marilyn Albert, at Harvard University, in collaboration with Dr. Moss has developed a new neuropsychological test. The test has been administered to a variety of patients with neurological disorders. This test seems to be of great value in the clinical diagnosis of AD. The results of this test have shown that AD patients have a significantly greater loss of information after a brief delay than other patient groups.

Preliminary results from the epidemiologic studies in East Boston suggest that dementing conditions among the older residents of that community are very common but rarely recognized by friends, family members, or even health care providers unless a specific effort is made to detect them and to establish a diagnosis. Of the cases of dementia which have been found in that community, approximately three quarters are attributed to Alzheimer disease, 10-15 percent to vascular causes, and the remainder to other or mixed causes. Current estimates suggest that the proportion of that community's elderly afflicted with dementia above age 85 exceeds 40%. It is not yet clear if this very high prevalence represents a finding which would be duplicated in similar communities were the same methodologies to be applied, if there is actually an excess of Alzheimer disease in this community, or if continued observation will result in a change in diagnoses, with rates being revised downward.

In the ethnically similar community of Framingham, Massachusetts, a somewhat more conservative approach to identifying the cases of dementia in the community is yielding rates approximately one-third those mentioned for East Boston. Whereas the objective of the East Boston Study is to understand the natural occurrence of the disease in the community, the purpose in Framingham is to utilize preexisting data on subjects there to identify risk factors for dementia. Differences in methodology may account for some part of the lower rates in Framingham.

Research is just beginning to focus systematically on how families and other social supports affect and are affected by Alzheimer disease (AD) and related disorders. More research is required along the lines recommended by the DHHS Task Force on Alzheimer Disease. Examples of such research include studies on the availability of family members to care for AD patients and actual caregiving behaviors; caregivers' perception of and response to AD symptoms; the influence of familial factors on the onset and course of AD symptoms; the burden of AD on caregivers; use of formal and informal support services to care for AD patients.

ALZHEIMER DISEASE RESEARCH CENTERS

Question. What have the Research Centers accomplished in the past year?

Answer. Research at the University of California, San Diego Alzheimer Disease Research Center (ADRC) indicates that between the ages of 20 and 100 there appears to be no significant decrease in the total number of nerve cells during the course of normal aging. The morphometric study of the cortex of 50 cases shows an increase in

glia, a decrease in large neurons and a corresponding increase in the number of small neurons. This finding indicates that the large neurons are shrinking and becoming part of the smaller size classes of neurons. Comparing these results with those obtained from Alzheimer disease (AD) patients between the ages of 50 and 70, Dr. Terry reports finding a greater loss of large and small neurons than found in the normal 70 to 90 year old groups. In addition, he has found that the younger AD patients display a significant loss of small neurons in the parietal and temporal areas. This was not seen in the normal older group.

At the Johns Hopkins ADRC, a study of post mortem brain tissue from AD and neurologically normal controls has showed that in AD the concentration of corticotropin-releasing factor like immunoreactivity (CRF-IR) are reduced in several areas of the cortex and there are reciprocal increases in CRF receptor binding. These results are very interesting because the observed changes are limited to some structures, while other areas of the cortex, e.g., cingulate cortex, are spared. These changes appear to interact with the cholinergic deficits in AD, as evidenced by the positive correlation between CRF-IR and choline acetyltransferase activity. It is speculated that the reduction in CRF-IR in the cortex of AD could result from selective degeneration of intrinsic cortical CRF neurons and/or disease of CRF neurons projecting to the cortex from other brain structures. Furthermore, the finding of an inverse relationship between a decrease in CRF-IR and up-regulation of CRF receptors shows a physiological relevance of the receptor site and provides another evidence that CRF acts as a neurotransmitter in normal cortical functions. This work opens another avenue to the study of brain chemistry in the clinical manifestations of AD.

Research at the University of Pittsburgh ADRC indicates there are significant variations in both morphological and cholinergic markers in the brains of AD patients. Investigators have found left to right hemispheric differences in the number of senile plaques and neurofibrillary tangles in four of five different brain areas examined. Lateralization of cholinergic differences, i.e., choline acetyltranferase activity, were particularly prominent in superior temporal cortex and the lateral basal nucleus of Meynert. As the investigators indicate, their results are preliminary and there is a need for further systematic studies on the lateralization of neuropathological markers of AD. Nevertheless, their preliminary findings indicate the need for caution in interpreting results from neuropathological studies that do not control for this significant source of variance in data.

At the Harvard-MIT-University of Massachusetts ADRC, a comparison has been made of Nuclear Magnetic Resonance, (NMR) and Computerized Tomograhy (CT) brain scans in twenty patients with dementia due either to multi-infarct or to AD. The results have led to three major preliminary conclusions: a) NMR scans are equal or superior to CT scans in defining cerebral spinal fluid (CSF) space, especially the cortical sulci; b) NMR scans are superior to CT scans in detecting small white matter lesions, especially lacunae and one unsuspected case of probable cerebral multiple sclerosis. NMR also provides greater detail of brainstem and posterior fossa structures; c) NMR brain scans permit direct imaging of structures of interest in AD, such as the hippocampus-amygdala complex. With CT scans,

conclusions concerning these structures are based on indirect estimates. In addition, NMR displays subcortical white matter thinning associated with cortical atrophy and ventricular enlargement. CT scans suggest cortical thinning only indirectly.

Investigators at the University of Pittsburgh ADRC, have been studying the relationship between language disorder, i.e., anomia, and abnormality of cholinergic neurotransmission in the brains of AD patients. The results suggest that AD patients have a semantic impairment characterized by inability to distinguish among objects that are members of the same semantic category, and that this impairment is linked with the anomia, difficulty in naming objects. Acetycholinesterase and butyrylcholinestrase activities in the cerebrospinal fluid have been measured in AD and control subjects. The results show that butyrylcholinestrase activity is decreased in AD and low activity is correlated with increasing severity of dementia, memory impairment and language disorder. Acetylcholinestrase activity is significantly correcated with visual contrast sensitivity but not with severity of the dementia.

In addition to research, the ten ADRCs have made progress in establishing strong ties with family groups and have begun to serve as a regional and national resource and referral source of expert advice. They have also begun to create a network of cooperating scientists who have begun to exchange information and establish national standards for diagnosis of AD. ADRC scientists have begun several collaborative studies among the centers. One noteworthy example of this is a multi-center study to find the genetic code for this disease. The ADRCs are now attracting gifts and donations from private philanthropists, and thus have begun to serve as magnets for a collaborative partnership between the Federal government and the private sector.

Question. I understand that there is some evidence that this disease may have a genetic base. Has it been possible to isolate and characterize genes responsible for Alzheimer's?

Answer. Some forms of AD have a strong genetic link. Utilizing families in which AD is inherited in an autosomal fashion, studies are underway in search of the specific genetic marker for AD. One such group from the Harvard-MIT-University of Massachusetts ADRC proposes to attempt the isolation of a specific and unique DNA fragment. However, in the current atmosphere of uncertainties about funding, it has been difficult to speed this area of research because well trained scientists in molecular biology find other areas of research such as AIDs or cancer less risky.

ALZHEIMER DISEASE RESEARCH

Question. Alzheimer's disease affects over 1.8 million Americans. How much is the NIH spending on Alzheimer disease research?

Answer. In FY 1985, the NIH spent $43.9 million on Alzheimer disease research. Of this amount, the NIA portion was slightly more than $28.8 million, or about 65.6% of the total.

ALZHEIMER DISEASE RESEARCH CENTERS

Question. How many of the 10 Alzheimer's Disease Research Centers mandated by Congress are in operation?

Answer. All 10 ADRCs are currently in operation.

Question. Is the funding level for these centers adequate? If not, how much more is necessary and how will this additional funding enhance the research efforts?

Answer. Under the 1986 revised budget, approximately $2.1 million in additional funds would be required to bring the Alzheimer Disease Research Centers up to the full recommended level. The shortfall in FY 1987 will be slightly higher, about $2.3 million.

Since inception of the ADRC programs, the full recommended funding level has consistently been higher than the funds available. Most ADRC Directors chose to minimize the effects of these short-falls by delaying the hiring of personnel essential to some projects, delaying the purchase of some equipment, postponing the start of some projects, and/or reducing the number of patients being studied or recruited for the clinical studies. Specific projects which have been delayed include, for example, a project to determine whether there are subgroups of patients within the classification of AD, to follow AD patients across time to identify possible behavioral and biological correlates of specific subgroups, a project to study the chemistry of neurofibrillary tangles, the primary brain pathology in AD; and a project to isolate a specific and unique DNA fragment from the genome of patients identified as manifesting familial AD. The University of Southern California ADRC had expected to study 13 patients per year including clinical assessment with a final autopsy. However, because of the tremendous desire of the family members to enroll in these studies, they have had over 40 patients during their first year of study and have a large number of brains which have been obtained for neuropathological studies.

FULL TIME EQUIVALENTS

Question. What impact is the reduction of full time equivalents (FTEs) in FY 1986 and 1987 going to have on your ability to conduct and manage the NIA research programs? Please be specific.

Answer. In FY 1984, the NIA used 379 FTEs. This was reduced to 356 FTEs in FY 1985. In FY 1986 and FY 1987, the NIA FTE ceiling is 340. By reducing staff in some administrative areas, it will be possible to maintain on-going extramural functions, such as grants and contract review and management, at much the same level as previously. Some extramural program areas may be subject to slower than desirable development due to inability to hire health scientist administrators with the requisite expertise. The NIA extramural program in molecular genetics will be delayed. The intramural research program will be able to maintain its highest priority areas, but will necessarily eliminate or reduce the scope of others. The new Laboratory of Molecular Genetics will not be fully staffed, most on-going intramural laboratories will lose staff and it will not be possible to add women to the Baltimore Longitudinal Study of Aging as rapidly as would otherwise be desirable. The new FTE level will also

affect NIA training goals by reducing the number of staff fellows -- all of whom fall under the FTE ceiling -- who can be hired.

HEALTH CARE COSTS AND PREVENTION

Question. Prevention, good nutrition, and effective functioning can help older individuals stay independent for longer periods of time and effectively reduce health care costs. What have you been doing in these areas?

Answer. Prevention presupposes knowledge. Fundamental to planning rational processes to maintain health during aging and to prevent the diseases so characteristic of older people is an understanding of the effects of secondary processes -- e.g., life style variables, disease, medications -- and their relationship to "primary" biological processes of aging. There is a dearth of understanding about the precise interactions of life style variables, aging, and disease. Thus, a major portion of the NIA extramural program and the whole of the Baltimore Longitudinal Study of Aging, which seeks to dissect the complexities associated with aging, are in a sense prevention related.

Research on nutrition is an NIA priority. One of the main goals is to understand the extent of nutritional deficiencies among the elderly. NIA-supported research at the University of New Mexico indicates that many older people are consuming far less than the current Recommended Dietary Allowances for vitamins B6, D, E, calcium, and other important nutrients. It is critical to determine the consequences of these low intakes. Research supported by NIA indicates that low levels of vitamin D and insufficient calcium intake are important causes of osteoporosis among the older population, that calcium and vitamin D requirements may change with age, and that calcium and vitamin D supplements may be helpful in preventing and treating this disease.

There are equally important questions about nutritional needs of older people for the prevention of other important diseases. For example, there has been considerable interest in zinc supplementation for older individuals based on indications that it may help to prevent infections. However, recent research supported by NIA indicates that zinc supplementation may increase risk for cardiovascular disease in some older persons. This finding highlights the need for knowledge of the full range of effects of nutrients in the older population in making nutritional recommendations for this age group.

NIA Baltimore Longitudinal Study on Aging (BLSA) cohorts are being examined for change in bone density, body composition, plasma lipids, nutrient intake, and the control of blood sugar by insulin and other hormones. A previous study of dietary intake of BLSA male participants over three consecutive five year intervals provided by far the largest experience on nutritional practices across the adult age span. This past year, dietary evaluations were reinstituted in men and initiated in women. Further, analyses of the beneficial role of dietary fiber on coronary risk factors and dietary variables as risk factors for cardiovascular death in very old men were completed. Another study concerns the pattern of distribution of body fat independent of total fatness. Distribution of body fat is emerging

as an important risk factor for diabetes, coronary artery disease, and mortality. NIA investigators have initiated a study designed to define the differential effects of obesity and patterns of fat distribution in adults at different stages of the life cycle. The effects of these variables on risk factors for coronary disease, on the development of obesity related diseases and on mortality will be assessed.

Intramural scientists are evaluating the immune function of BLSA participants to determine age-associated changes and the possible effects of these changes on the incidence and type of disease. Intramural scientists have also launched a major collaborative study to examine the relationship of age and physical activity to endocrine-metabolic and cardiovascular function in highly-trained elderly individuals (senior athletes) as compared to a sedentary population. Information derived from this study when completed should provide insight into the potential benefits of aerobic exercise conditioning programs for sedentary middle-aged and older people and may be useful in determining optimal exercise prescriptions for such individuals. Investigators with the intramural Laboratory of Personality and Cognition have contributed new insights about the stresses faced by aging adults, the methods and strategies used by them to cope, and the effectiveness of their coping efforts. Psychological stress has long been considered a possible contributor to a number of illnesses, and several interventions have been designed to reduce stress and thus promote health.

A variety of studies has demonstrated the importance of behavioral and social factors in the causes, prevention, diagnosis, treatment, and recovery from illness in later life, as well as in the maintenance of health over the life course. In order to further specify and allow the translations of findings into actions, the NIA is encouraging the development of behavioral geriatrics research as a new area in behavioral medicine. Research is being solicited and supported on a) the origins, nature, and mallability of health-related attitudes and behaviors of older people and health providers, b) "illness behaviors" such as how older people monitor their bodily functioning and what determines whether they take what kinds of remedial actions, c) cohort and longitudinal studies on the effects of life style, personality, and life stresses on morbidity and mortality, d) the role of informal care provided by the family, friends, and neighbors vs. formal care by organizations, e) the design and evaluation of behavioral therapies as alternatives to surgical or pharmacological treatments (e.g., for urinary incontinence), and f) the specification of physiological processes intervening between social and behavioral factors, on the one hand, and health outcomes on the other.

Intellectual functioning, memory, perception, and psychomotor skills are central to maintaining effective functioning and health as people age. NIA-research continues to demonstrate that few healthy individuals up to age 60, and less than half even at age 80, show reliable aging decrements in cognitive test performance. Current research is focusing on identifying aspects of functioning that change or remain stable and specifying the biological, psychological, and social processes influencing them. This research is also exploring the extent to which intellectual, cognitive, and

sensorimotor performance can be maintained or improved through interventions.

The NIA also supports a program in exercise physiology which is oriented towards dealing with how biological adaptative processes are influenced by aging and how systematic programs of physical activity impact on age-related disorders and processes such as maturity onset diabetes, bone loss, and hypertension. Recent studies supported by NIA have demonstrated major beneficial outcomes from systematic endurance type training in most older men and women. Research is needed to assess the mechanisms through which acute exercise and especially regular, long-term physical training prevent, ameliorate, or, in some cases, exacerbate age-associated conditions, diseases, and disorders. For example, recent observations by an NIA grantee suggest that undesirable age-related changes in carbohydrate metabolism and glucose tolerance are overcome through systematic physical activity programs. For the immediate future, the focus of exercise physiology research will be placed on cardiovascular-respiratory function and fitness, skeletal muscle performance and capacity, and the relationship between increased work capacity and health status.

RESEARCH OPPORTUNITIES

Question. Are there research opportunities that are not being exploited?

Answer. One of our greatest needs is for clinical nutrition studies which will allow us to translate the promising findings to date into practical recommendations, such as the Recommended Dietary Allowances (RDAs), which can be used by older persons and by policymakers involved in health and nutrition programs for the elderly. The current dietary allowances are not adjusted for the elderly, and prevention of the chronic diseases of aging has not been used as a criterion in setting them. This situation needs correction. For example, though we have increasing evidence that the RDAs for calcium are too low to prevent osteoporosis in older women, we do not know exactly how much to recommend, nor do we know whether different recommendations are needed for different age groups among the elderly. Similar questions exist for many other nutrients, for example on the role of B vitamin deficiencies in dementia. Sounder recommendations for older people about these nutrients could result in great improvements in health and reductions in health care costs.

A number of other promising research areas also cannot be fully exploited at this time. For example, research on applying the field of human factors to the problems of the elderly is underdeveloped. Although there is a substantial body of data describing various aspects of cognitive and sensory aging, there is a need for research to provide insight into the functional significance of these changes, retraining strategies, and new technologies to aid aging people. The NIA has been successful in attracting high quality scientists to the study of visual perception. Similar research is required on auditory perception, but will not be developed under existing funding constraints. Development of improved methods for forecasting the life expectancy and active life expectancy of people as they age, especially of the oldest old, also cannot proceed as rapidly as is desirable. Such methods are needed in order to more adequately plan

for the health care requirements of the aging U.S. population. Finally, longitudinal studies are needed to determine the role of exercise in promoting health and preventing disease. Such studies would be challenging to design and expensive to maintain.

NIA intramural scientists have developed a collaborative venture with Johns Hopkins to study immune responses of older individuals to different types of influenza vaccines. The study was planned to begin in FY 1986, but has been cancelled due to lack of funds. Influenza is the fourth leading cause of death in the older population, and many vaccines -- the efficacy and safety of which were established in the military and children -- are not efficacious for older people. By using vaccines that inspire humoral, cellular and/or mucosal immune response in in vivo situations, the extent and type of age related immunodeficiency may be determined. It is anticipated that the study will proceed in children as previously planned, but, given the disengagement of NIA, not in the older population.

Question. Given the current budget proposal, will you be able to maintain your activities in these areas at previous levels?

Answer. Every effort will be made to maintain research on these topics at the highest level possible. They must, however, be considered in light of other high priority areas -- Alzheimer disease, osteoporosis, and training, for example.

EPIDEMIOLOGICAL STUDIES

Question. I understand that you have established studies in four separate communities to learn more about the health of the elderly. Have differences been observed between these communities? Are these differences related to environment, prior economic status, or to something else?

Answer. The studies you refer to are the NIA's Established Populations for Epidemiologic Studies of the Elderly, located in Iowa, New Haven, East Boston, and North Carolina. We do not as yet have data from the North Carolina study since it only began last year and the data are just now being collected. We have noted major differences in some aspects of health between the other three sites. In general, the proportions of older people being treated for hypertension or heart disease in the three communities are very similar while physical and cognitive impairments are substantially more prevalent in East Boston and least prevalent in Iowa. The hypothesis we are now testing is a conservative one: that the reason for the difference is NOT that one place is more beneficial for health than another, but instead that the greater affluence, smaller family size, and perhaps social factors existing in Iowa act to select the healthiest older people to remain in the community while the less independent move from the community to other places where their needs for help are more easily met. In contrast, the lesser affluence, large families, urban housing, and cultural milieu of East Boston may allow the partially or fully dependent older individuals of that community to remain in their own homes or the homes of friends or family members. The culture and conditions of New Haven are hypothesized to be intermediate between these extremes. If this hypothesis is not confirmed, we will then consider possible

hypotheses related to true health-promoting differences between the communities involved in these investigations.

OSTEOPOROSIS AND OSTEOARTHRITIS

Question. Osteoporosis and osteoarthritis are conditions that especially afflict the elderly. How much is being spent on research in these areas?

Answer. In FY 1985, NIA support for research on osteoporosis totalled approximately $3.3 million for studies directly focused on this disorder. An additional $2.9 million was spent for studies of risk factors for osteoporosis and related problems such as hip fracture. NIA support for research on arthritis, including osteoarthritis, was $1.6 million.

Question. Are we making any progress?

Answer. Progress is being made on osteoporosis. Recent data indicate that bone loss in women may begin even before menopause, possibly as early as age 35. This may have important implications for the timing of strategies for prevention and treatment. We have also learned that thiazides -- widely used diuretics -- are also effective in protecting against bone loss. New data suggest that women who discontinue estrogen use may lose bone mineral even more rapidly than women who have never used estrogens. This is another finding with important implications for the onset and duration of treatments. Recent careful studies have shown that vigorous exercise (including walking) can decrease the loss of bone in post-menopausal women. NIA, in cooperation with the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), recently funded a major multi-center study of the risk factors for hip and other fractures. A total of 9,600 women will be studied prospectively to determine the factors which lead to fractures and loss of bone mass.

Progress on osteoarthritis has been depressingly slow. We have seen some advances in our basic knowledge of structure and biochemistry of the tissues which are damaged in osteoarthritis. However, there has been little progress in moving from this knowledge to an understanding of what causes the disease or how to prevent it. We face a shortage of researchers and grant applications on these topics. NIA and NIAMS co-sponsored a conference in 1985 which identified some promising leads for research. We hope to launch an initiative for funding this research in FY 1987.

Question. We see advertisements for calcium replacement therapy in the media. How important is this therapy?

Answer. The issue of calcium replacement therapy is important, especially since women, who are at high risk for osteoporosis, tend to consume less than the current Recommended Dietary Allowance (800 mg daily) for calcium, and far less than recent NIH Consensus Conference recommendations. The NIH Consensus Conference recommended 1000 mg daily for pre-menopausal and estrogen-treated post-menopausal women, and 1500 mg daily for post-menopausal women who do not receive estrogen. Calcium supplementation is a particularly important issue for older women since calcium intake tends to decline with increasing

age from a high of about 680 mg per day on average at ages 18-24 to a low of about 540 at ages 65-74.

The NIH Consensus Conference recommendations are our best estimates of the amount of calcium needed to protect against osteoporosis. To achieve these levels in the diet requires either supplemental calcium or a very large intake of dairy products. We need more information on which sources of calcium are best for optimal health of older people. We also need much more definitive data to make specific recommendations for prevention strategies. For example, it is still not firmly established that increased calcium intake will retard bone loss in postmenopausal women, and if so, how much is needed. In view of the fact that calcium absorbtion declines with age, we need to know if calcium intake should gradually increase throughout the later years of life. These issues are important, since optimizing calcium intake could be a safe and cost-effective way of preventing or minimizing osteoporosis.

THE OLDEST OLD

Question. The oldest old, those senior citizens over the age of 85, are increasing in numbers in our society. What research is being conducted in this area and at what cost?

Answer. Despite Federal expenditures of between $50-60 billion for those over age 80 and the very heavy burden of morbidity, little is known about the oldest old in comparison with the young old. NIA research is progressing along two fronts: creation of data sets and encouraging extramural research projects.

Studies of the oldest old are complicated by the lack of quality data. Since the 85 plus now constitute only about 1% of the population, most surveys do not contain adequate numbers for detailed analysis. The frailties often encountered within the oldest old population also complicate the research process. Through Inter-Agency Agreements with the Bureau of the Census and the National Center for Health Statistics (NCHS), the NIA is endeavoring to improve the data on those 85 plus that is available to extramural and intramural researchers. NCHS and NIA are conducting the Longitudinal Study on Aging, which is a re-interview of the very old who participated in the Supplement on Aging (SOA) of the 1984 National Health Interview Survey (NHIS). This study will provide information on the transition between independence and dependency, and an historically organized data tape of the Health Interview Survey will allow for the analysis in health trends among the oldest old.

The Bureau of the Census and the NIA are preparing special tabulations on the older population from the 1980 Census and an international database on aging. The latter will provide information on comparative aspects of the sudden growth of this population. These data sets are being made available to the scientific community through the NIA-supported National Archive of Computerized Date on Aging at the University of Michigan. FY 1986 expenditure for these four interagency agreements are approximately $252,000.

Progress in funding extramural research has been slow. Data are being collected on the oldest old through the NIA population

contracts but, while the NIA issued a program announcement in December, 1984, soliciting research proposals on the oldest old, only now are fundable applications being received. The topics covered by currently funded research grants include demographic analyses of multiple causes of death, the demography of the extreme aged, trends in morbidity, and the changing composition of the oldest old. It is expected that at least two more projects will be funded during the remainder of FY 1986.

Question. Given the expected increase in size of this segment of our population, are you doing enough research?

Answer. We have taken notice of the changes in the distribution of the elderly population and have begun important research in this area. There is more work to be done. Examples of such work include: forecasting life and active life expectancy and development of realistic projections of the future size and composition of the Nation's 85 plus population, including future patterns of mortality, morbidity, and the need for care; sex and race differentials in morbidity and mortality at advanced ages; paths to poverty; the development of methodologies to study the oldest old; and projects that utilize the data sets that are being developed.

Question. How much more funding would be necessary to fully address the problems of the oldest old?

Answer. To take advantage of the readiness of the science and scientists in this area -- data bases, individual research grants and workshops, and epidemiological studies -- would require approximately $3.2 million in additional funds in FY 1987.

MOLECULAR GENETICS

Question. What is the status of the laboratory and are you requesting enough funds to bring it to full capacities?

Answer. The Laboratory of Molecular Genetics (LMG) commenced operations in October 1985. The LMG has been successful in attracting two very talented young researchers to join its staff. One additional independent scientist is being recruited.

The LMG is initiating a number of projects to investigate the molecular basis for aging and age-dependent diseases. In one project, Dr. Holbrook of LMG is collaborating with Dr. Adler to examine the molecular basis for the decline in immune function that occurs with human aging. They are looking specifically at the expression of the interleukin II gene. Interleukin II is a factor which confers immune function to human lymphocytes enabling them to mount an effective immune response. Studies in Dr. Adler's laboratory at the Gerontology Research Center, NIA have shown that the production of interleukin II declines in lymphocytes from older human volunteers. The LMG, together with Dr. Adler's group will attempt to discern the molecular basis for this decline. We anticipate that this approach may yield opportunities to slow down the immune decline with aging and help agument the response of older Americans to infections. Another project involves the study of genes that may be related to Alzheimer disease.

No additional funds have been requested for FY 1987. To remain within the President's budget, we will keep staff recruiting to the current levels and will maintain a reduced level of effort to meet the FY 1987 budget goals.

Question. How much more will be needed in the FY 1987 budget?

Answer. To bring the staffing levels of LMG to initial staffing projections would require an additional four FTE's and to reach initial plans for equipping this laboratory would require an additional $500,000 in FY 1987.

BALTIMORE AGING STUDY

Question. Can you give us a status report on the Baltimore Longitudinal Study of Aging?

Answer. The Baltimore Longitudinal Study of Aging (BLSA) is a unique resource to study human aging. The study population is a group of community-dwelling volunteers ranging from 20 to 95 years of age. Currently, there are 613 active male participants and 345 female. The subjects return every two years for re-evaluation and are enrolled for their lifetimes. The male study is now in its 28th year and the study in women its 8th year. Recently, the study was given heightened organizational status as part of an intramural reorganization. In October, 1985, Dr. James Fozard assumed the role of BLSA Associate Scientific Director.

Consistent with the overall BLSA goal of systematically describing the processes of aging in humans, BLSA subjects are intensively studied for physiological and behavioral changes occurring over the entire adult life span. The patterns of age changes are identified; age norms are defined; mechanisms underlying the changes are elucidated; and disease-aging interactions are evaluated. Much has been learned through the BLSA, and a multitude of intriguing opportunities for further research identified. The BLSA has made clear the complexity of aging processes. Researchers now emphasize the need to consider the interacting influences of biological processes, personality and behavioral factors, social and environmental forces, and the idiosyncratic health behaviors and stresses of the individual. The multidisciplinary approach incorporated in the BLSA study design is suited to such investigations.

Renewed emphasis is being given to promoting collaborative studies, increasing the utilization of BLSA data which constitute the single greatest resource of information on normal aging, and exploring the interactions of aging with life style variables through comparative analyses with other populations. Examples of collaborative studies include plans to initiate a BLSA autopsy program with Johns Hopkins and introduction of a BLSA oral physiological component in conjunction with the National Institute of Dental Research. Opportunities to utilize the accumulating data from multiple subjects over time are exemplified by the possibility of studying the overall characteristics of successful aging. BLSA data base analyses may serve to identify relationships among the individual biological and behavioral measures which seem to differentiate those individuals who appear to show relatively large

decrements in age related variables from those who show the least. Participants so identified would be singled out for special study on succeeding visits.

Question. Are you requesting enough funds to continue the study in FY 1987?

Answer. Adequate funds have been requested to maintain the Baltimore Longitudinal Study on Aging.

Question. Will insufficient funding cause the loss of important data?

Answer. Replacement of study participants lost through deaths and drop-outs, and recruitment of new BLSA participants, specifically women and both males and females aged 75 and older, will be curtailed. Further, at this funding level, it would not be feasible to follow those BLSA participants who become too ill to return to Baltimore for their biennial visit, and the data that would otherwise be obtained at this critical juncture in these subjects' lives will be lost. A longstanding BLSA recruitment goal has been to increase the number of women so as to equal the size of the male sample. Recruitment of women began in 1978, but has proceeded at a slower than desirable pace. At the present recruitment rate, a minimum of seven additional years will be needed to reach this goal. The costs of this prolonged approach encompass both slowing the pace of discovery and foregoing opportunities. Longitudinal analyses which could provide insights into gender differences in disease development and longevity must be deferred. Specific outcome variables will be so few in the female cohort that the search for new precursors or risk factors may not succeed. Therefore, it had been planned to move up the pace of recruitment of women so that 150 would be added in FY 1987. To keep within the administration's FY 1987 budget, only 25 women can be added in FY 1987.

Plans to have longitudinal analyses of selected BLSA data sets performed will necessarily be deferred. Staffing shortages preclude in-house analyses of certain data sets (e.g., pulmonary function, history and physical, hearing, motor skills), and an alternative approach had been to use professional service contracts to ensure timely analysis of accumulating BLSA data. The decrease in the projected budget for FY 1987 will not permit utilization of the contract mechanism.

The BLSA provides a unique opportunity to serially study gender differences in several critical areas including osteoporosis, strength, metabolism, personality and coping, and time of onset of age-related disease. The BLSA has the potential to lay the basis for insights into the remarkable but still unexplained difference in disease development and longevity between the sexes. Opportunities that could be pursued with additional resources include: (1) undertaking follow-on studies to capitalize on promising results and the introduction of new technologies (e.g., access to a NMR imager will enable measurements of cardiac mass and ventricular hemodynamics in BLSA subjects to build upon recent findings about the effect of age on cardiac structure and function); (2) research on antecedents of frailty in healthy people; and (3) use of the BLSA as a source of research experience for physicians in academic medicine who have

clinical training in geriatrics but lack the research background necessary to their career advancement.

Question. How much more will be necessary to conduct the study as effectively as possible?

Answer. To conduct the BLSA as effectively as possible would require an additional eight FTE's and $600,000 in FY 1987.

IMPACT OF BUDGET REDUCTION

Question. The President's budget proposal for FY 1987 reduces your budget by $10,662,000 under FY 1986 appropriated levels. Gramm-Rudman-Hollings, if triggered, could reduce your budget even further maybe by as much as 20 percent. I've known this would reduce the number of grants, possibly the size of grants, centers, training, etc., etc. Can you give us some idea of the impact of these reductions on the kinds of research that would be stopped or lost?

Answer. The NIA does not have a specific contingency plan for additional reductions below the current FY 1987 President's budget. An additional 20 percent reduction below the President's budget would certainly affect all NIA programs to some degree. Very serious thought would have to be given to eliminating lesser priority research programs altogether.

Question. What impact might this have on the health of our citizens five and ten years down the road?

Answer. It is not really possible to quantitatively predict the consequences of such reductions on the health and well being of older people five or ten years from now. However, reductions of the size suggested would significantly reduce the amount of biomedical research performed by investigators in the field of aging. This investment in research on aging and aging-related health problems has a direct impact on the future availability and efficacy of new health diagnoses, preventions, and treatments.

GRAMM-RUDMAN-HOLLINGS

Question. If the automatic provisions of Gramm-Rudman-Hollings are triggered in FY 1987, your Institute may well have its budget reduced by 20-25%. Have you prepared a contingency plan in the event Gramm-Rudman-Hollings becomes reality? If so, please send a copy of your plans to this committee.

Answer. The President's budget was developed within overall deficit targets that would preclude the need for sequestration in FY 1987. Therefore, the NIA has not developed a contingency plan to deal with reductions below the 1987 President's budget.

Question. If cuts of this magnitude become reality, how will they be distributed:

1. Intramural vs. Extramural programs.
2. Peer review system;
   Would number of site visits be reduced?
   Would travel to NIH to study section meetings be affected?

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3. Would NIH employees have to be furloughed?
4. What major programs would have to be cut back?

Answer. If further cuts became a reality, all programs would be affected. Lower priority programs would be cut most severely and serious thought would be given to eliminating at least some research activities altogether.

Question. Please list the research programs of the highest priority that should not be cut and why.

Answer. Until a full review of all programs is done, it is not possible to identify those programs that should not be cut at the levels you mentioned.

Question Submitted by Senator Arlen Specter

ALZHEIMER DISEASE

Question. Dr. Williams, your statement refers to Alzheimer's disease as a "silent epidemic" and points to findings of researchers at Pennsylvania State University, Harvard and NIH that have suggested that the cost, both direct and indirect, could reach $77 billion per year. What knowledge has the National Institute on Aging gained in preventing this disease and what public education programs exist or are planned with this data?

Answer. At present, we do not have the necessary scientific knowledge for preventing Alzheimer disease. Research supported by the National Institute on Aging and other institutes related to prevention includes the role of familial (genetic) factors in some cases, the role of head trauma, and the likely role of very high intake of aluminum. It is only after we understand how the disease comes about that we can hope to develop measures to prevent it.

In the meantime, we have initiated and built a strong public education program focusing on changing public needs: first, helping the public to recognize that senility is not a part of normal aging; next, helping them to recognize and identify Alzheimer disease; now, helping to spread the latest information on what might cause the disease, how it progresses and what can be done to help the patient and the family; and, when it becomes appropriate, spreading the word on how the disease can be cured and prevented. With these goals in mind, our information and our educational materials on Alzheimer disease have been distributed to several million individuals--through NIA distribution channels as well as through the Alzheimer's Disease and Related Disorders Association (ADRDA), the American Association for Retired Persons, and major national and local media.

We have recently begun talks with public affairs experts at the University of Pittsburgh Alzheimer Disease Research Center (ADRC) to develop a new means of translating and disseminating the latest information on Alzheimer disease. It is our plan that the 10 currently funded ADRC's will work together--and will develop ties to local ADRDA chapters--to form a strong national network for public education in the area of Alzheimer disease.

Although prevention of Alzheimer disease may be years away, we feel that our research knowledge has helped us develop public education programs that have prevented people from accepting senility as normal, prevented the unnecessary institutionalization of misdiagnosed individuals, and prevented Alzheimer families from losing all hope.

DIVISION OF RESEARCH RESOURCES

STATEMENT OF DR. BETTY H. PICKETT, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

DR. JAMES F. O'DONNELL, DEPUTY DIRECTOR, DIVISION OF RESEARCH RESOURCES

DENNIS P. WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

OPENING REMARKS

Senator WEICKER. Next we deal with research resources, and we have Dr. Pickett here.

Jim, what is the degree of coordination in the sense of how many people, for example, in the Blood and Heart Institute are working on aging, how many in the Cancer Institute are working on aging? In other words, this really crosses so many disciplines. What is the sense of coordination here?

Dr. WYNGAARDEN. I can give you a more precise answer about Alzheimer's than aging in general. With Alzheimer disease there are four or five groups that are involved in one way or another. The Aging Institute is probably the largest, with $32 million.

The Neurology Institute has about $13 million in Alzheimer's studies, allergy about $1 million, research resources just under $1 million, and the Heart Institute has one grant that is considered Alzheimer's type work, and, of course, the Mental Health Institute has a large program in Alzheimer's. We have an Alzheimer's coordinating committee that keeps communication up to date.

Within the Aging Institute there is a lot of informal interaction. For example, the Aging and the Heart Institutes are supporting a clinical trial on systolic hypertension in the aged. I suspect Dr. Williams could give other examples of where there are such opportunities. There are many, many linkages.

Senator WEICKER. Thank you very much.

PREPARED STATEMENT

Dr. Pickett, please introduce your colleagues, and your statement in its entirety will be placed in the record, and you can proceed in whichever way you like.

[The statement follows:]

Statement of Dr. Betty H. Pickett

I am pleased to present the 1987 budget request for the Division of Research Resources (DRR).

The Division provides for the development, support, and administration of research resources which complement and augment NIH's extramural research project grant, research contract and research training activities by operating five distinct programs.

The Clinical Research Program continues to provide specialized environments and resources necessary for the conduct of high quality clinical research through a nationwide program of General Clinical Research Centers. Seventy-six Centers will be supported in 1987. Research advances include important discoveries in relation to glaucoma, high blood pressure, diabetes, cancer, and multiple sclerosis (MS). For example, a synthetic substance called Copolymer I reduces the number of attacks of MS and arrests the progression of disability. New studies now show that an insulin-containing nasal spray may be an important adjunct to injections for insulin delivery. Eighteen General Clinical Research Centers supported work on AIDS, including studies of opportunistic infections in immunocompromised patients, epidemiological studies of AIDS patients, and therapeutic interventions for both the primary disease and secondary infections.

The Centers provide an outstanding environment for the research training of young physicians through the Clinical Associate Physician (CAP) appointments. Forty-seven were appointed in 1985. Overall, 130 young physicians have served as CAPs since 1974; all but 14 remain in academic positions, and 57 have obtained NIH research grant support.

Emphasis on three areas of the Clinical Research Program will continue in 1987: electronic communications among Centers, the use of outpatient research protocols, and the clinical research data management and analysis system (CLINFO).

The Biomedical Research Technology (BRT) Program supports research centers, resource-related research projects, and research contracts in three program areas: computer resources, biomedical engineering, and biological structure and function. Examples of research accomplishments follow.

Computers simulate toxic and carcinogenic effects of chemicals in an effort to set realistic safety standards for the environment and for human consumption. Investigators supported through the BRT Program are seeking methods for comparing chemical and physical properties of new compounds with those of known toxic substances.

Three-dimensional information about the structure of cells, cell clusters, nerve nets, and tumors is vitally important in the understanding of hormone production, the progress of cancer, or the causes of many diseases of the nervous system, among others. Now, BRT researchers have developed ways to obtain this information

through use of very advanced computer hardware and automated pattern recognition techniques in experiments in brain and tumor anatomy.

In a major advance, rhinoviruses, responsible for the common cold, turn out to have very similar structures to both human poliovirus and some plant viruses. It may be that the similarities indicate similar modes of action. The researchers involved in this discovery used the DRR-sponsored synchrotron radiation resource and a supercomputer.

DRR's Laboratory Animal Science and Primate Research Program comprises three components: the Regional Primate Research Centers, the Laboratory Animal Sciences Program, and the Biological Models and Materials Resources Program. The report requested by the Committee on the needs of the Primate Research Centers details the timetables for renovations and improvements required for continued effective operation of these major research resources.

Research continues in several Primate Research Centers on simian acquired immunodeficiency syndrome (SAIDS). Rhesus monkeys may well provide an excellent model for development and testing of vaccines against retroviruses. The California Center has already succeeded in developing a vaccine that apparently fully protects monkeys against SAIDS. Development of this vaccine will not only benefit the health of the animals but will also further our understanding of how to develop protection against human AIDS. Examples of other research accomplishments in the Centers are: effects of alcohol consumption during pregnancy, and prevention of spread of monkey pox in a colony of rhesus monkeys following the use of a fluorinated pyrimidine compound.

The Laboratory Animal Sciences (LAS) Program assists institutions to develop and improve animal resources for biomedical research. For example, LAS awards support research on animal diseases, because healthier animals are better research subjects. Maintenance of special colonies and development of animal models assure that important animal resources are available. Resource laboratories are supported in order to improve animal health programs at research institutions. Grants are awarded for training in laboratory animal medicine to assure that key personnel will be available for critical research.

In 1985, DRR initiated a major change in the Animal Facilities Improvement Grants program to assist institutions in complying with requirements for both the Animal Welfare Act and new Department policy on the care and treatment of laboratory animals. For the first time, renovations within facilities improvement awards could be funded in amounts up to $500,000; matching funds were required under the program's guidelines. Twenty-three institutions received improvement awards in 1985; in both 1986 and 1987 approximately nine additional awards will be made.

The newly developed Biological Models and Materials Resources (BMMR) Program supports the research resources which rely on cell systems, lower organisms, and nonbiological models. Support for five such resources initiated in 1985 will continue in both 1986 and 1987.

Since 1972, the Minority Biomedical Research Support (MBRS) Program has addressed the needs of minority research institutions, faculty,

and students. In 1985, two new MBRS grant initiatives were instituted; the Thematic Grant provides support for the work of a group of investigators developing research organized around a theme; the Undergraduate College Research Participation Award supports a variety of "enrichment" activities (including visits to the institutions by outside scientists and attendance by students and faculty at scientific meetings and seminars) and individual pilot research projects for faculty. Both new initiatives, as well as the traditional multi-project, multidisciplinary MBRS awards, are continued in 1986 and 1987. Newly available data indicate that 199 former MBRS students have received Ph.D. degrees, 94 have received D.D.S. degrees, and 617 have received M.D. degrees.

The three subcomponents of the Biomedical Research Support (BRS) Program are the Shared Instrumentation Grant, the Minority High School Summer Research Apprentice Program, and the Biomedical Research Support Grant. One hundred seventy-one BRS-Shared Instrumentation Grants were made in 1985; another 156 will be awarded in 1986. These grants support the purchase and installation of sophisticated research equipment that can be shared by groups of PHS-funded investigators. This program is directed at alleviating instrument obsolescence or shortages in the nation's biomedical research laboratories. Equipment purchase between $100,000 and $300,000 is supported. Since 1982 more than 550 research instruments will have been supported. Approximately 200 applications are pending review for funding in 1987; of these we anticipate funding approximately the same number of awards as in 1986.

The Minority High School Summer Research Apprentice Program provides $1,500,000 to approximately 270 research institutions annually to support summer research experiences for 1,000 high school students. The students work for eight weeks in laboratories under the supervision of biomedical researchers; the hope is that apprentices will become aware of the possibility of health research as a career option.

The Biomedical Research Support Grant (BRSG) Program provides flexible funds whose use is determined by the institution. Giving research institutions the opportunity to allocate funds locally enables them to respond quickly to unexpected needs or a sudden change in research emphasis, and to provide seed money in pilot projects for exploration of new theories or techniques. In view of the growing concern for budget control, the Biomedical Research Support Grant Program, is being proposed for elimination in 1987. This program which provides generalized institutional support is of lower priority in comparison to other NIH programs which focus research funds in specific problem areas. In order to assure continued support to research investigators at those institutions most heavily engaged in biomedical research, grantee institutions will be encouraged to require more sharing of resources and facilities, allow more release time for investigators to conduct pilot research activities, initiate institutional development programs for new investigators, and seek additional funds from within the institution and other private sources.

Mr. Chairman, the request for the Division of Research Resources for FY 1987 is $234,192,000. I'll be pleased to answer your questions.

Biography of Dr. Betty H. Pickett

Date and Place of Birth: February 15, 1926, Providence, Rhode Island
Marital Status: Married to James McPherson Pickett, 1952

Education: 1945 - A.B. (Psychology) Magna Cum Laude, Brown University
1947 - Sc.M.(Psychology) Brown University
1949 - Ph.D.(Psychology) Brown University

Positions Held:

September 1949 - March 1958: Assistant Professor at University of Minnesota and University of Nebraska; Lecturer in Psychology, University of Connecticut; Professional Associate, Bio-Sciences Information Exchange, Smithsonian Institution, Washington, D.C.

March 1958 - March 1961: Executive Secretary, Behavioral Sciences Study Section; Executive Secretary, Experimental Psychology Study Section, Division of Research Grants, NIH.

August 1962 - June 1977: National Institute of Mental Health: Research Consultant to Mental Health Unit, Region #1; Executive Secretary, Research Career Program; Chief, Cognition and Learning Section, Behavioral Sciences Research Branch; Deputy Director, Division of Extramural Research Programs; Director, Division of Special Mental Health Programs; Acting Director, Division of Extramural Research Programs.

June 1977 - January 1979: Associate Director for Extramural and Collaborative Research Program, National Institute on Aging

January 1979 - July 1981: Deputy Director, National Institute of Child Health and Human Development

July 1981 - July 1982: Acting Director, National Institute of Child Health and Human Development

July 1982 - September 1982: Deputy Director, National Institute of Child Health and Human Development

October 1982 - Present: Director, Division of Research Resources

Professional Societies: American Psychological Association; Eastern Psychological Association; Psychonomic Society; Association of Women in Science; American Association for the Advancement of Science; Academy of Behavioral Medicine.

Honors, Awards: Phi Beta Kappa, 1945. Sigma Xi, 1945. University Fellowship, Brown University, 1947-48. A.B., Brown University, Magna Cum Laude, high honors in psychology. DHEW Superior Service Award, 1972. DHEW Distinguished Service Award, 1975. FEW Award for Distinguished Service in Support of Equal Opportunities for Women, 1975. Citation from Graduate School, Brown University for scientific and professional achievement, 1978. Harold M. Hildreth Award, 1979, American Psychological Association (for distinguished contribution to psychology in the public service). Senior Executive Bonus Award for outstanding performance, 1981, 1982, 1983 & 1984.

INTRODUCTION OF ASSOCIATE

Dr. PICKETT. Thank you, sir. This is Dr. James F. O'Donnell, the Deputy Director of the Division of Research Resources.

I will just make a very brief statement. The Division of Research Resources is a diversified and important part of the NIH research portfolio. We provide, as you know, research environments and facilities, instruments, technologies, experimental animals, and skilled manpower.

The resources that DRR provides are utilized by some 18,000 investigators who are engaged in over 5,000 grants supported by close to $800 million in NIH funds. Some of the research conducted within these resources is by core staff who operate and develop the resources, and some of it is conducted by investigators supported by grants from the categorical institutes.

The general clinical research centers, of which there are 78 in 1986, are active across the board in disease categories from AIDS to diabetes to cancer and infectious diseases. We have a new center that is entirely focused on aging established at the Francis Scott Key Hospital in Baltimore in conjunction with the Johns Hopkins University. It is jointly funded by DRR and NIA and it will focus its attention on cardiovascular studies, neuroendocrine studies, and immunology with special interest in the effect of exercise on glucose tolerance and blood pressure.

The biomedical research technology centers focus their attention in three areas: computers, bioengineering, and instruments for analysis of biomolecular structure and function. The centers are regionally and nationally focused. They are installations where investigators from other institutions can bring samples and learn about the technology.

Our Animal Resources Program provides a variety of animal models. Seven regional primate centers provide many species of subhuman primates and excellent facilities for conducting research on them.

Our laboratories for animal health study diseases of animals used for laboratory research, and attempt to provide the healthiest possible animals for research so that there will be no confounding factors in interpreting the results.

Some of our funds are used for renovation of animal facilities, and in 1985 we supported an initiative on improving these laboratory animal facilities.

Training is an important aspect of the animal resources program; training in laboratory animal sciences. Some of the trainees that Dr. Williams just referred to that are supported in training programs of other institutes are supported in some of the DRR lab animal science institutional training grants, because, of course, there is great interest in the aging animal as a model for human aging.

The Shared Instrument Program, which has been operated since fiscal year 1982, provides state-of-the-art high-technology instrumentation that can be shared by groups of investigators ranging from 3 to 30. We have awarded nearly 100 million dollars' worth of such instruments through approximately 550 instrumentation grant awards.

Minority group participation in biomedical research is a slightly different aspect of our resource provision. It deals with developing human resources. The funds support minority institutions, faculty, and students. The most recent data we have developed on student outcomes shows us that so far, of the 7,500 minority students who have been in the program since 1972, more than 900 have received doctoral degrees in the sciences, medicine, and dentistry, and there are many more in the pipeline.

We are planning, as part of the NIH centennial observance, to schedule our annual minority biomedical research symposium at the same time as the focal NIH celebration in October 1987.

Our Minority High School Student Research Apprentice Program is a very small program but one that has considerable power for interesting students in careers in biomedical research. One thousand students are being supported annually in guided research experiences in laboratories in nearly 300 institutions.

Four of these students last year figured very well in the Westinghouse science talent search. One was a winner, one was a runner-up, and we had two semifinalists. Just one other note about that. Two such students were in Dr. Herbert Hauptman's lab at the Medical Foundation of Buffalo. He was one of last years Nobel Prize winners. It is an interesting and important program for $1.5 million.

Our budget request for 1987 is $234,192,000, which is a reduction of $56.6 million below the revised 1986 level.

I will be pleased to answer your questions.

ANIMAL WELFARE ASSURANCES

Senator WEICKER. We read an awful lot, see an awful lot about the Animal Research Program. Why don't you bring me up to date on where we stand. I am a little confused as between those who feel that there should be better treatment of the animals and I also recognize the necessity of all animals for research. I think all of us want to see that what is done is done under the most careful and humane circumstances. I gather that is not the case.

Dr. PICKETT. It may not be the case in certain isolated instances that have been identified. Certainly all of us want high quality treatment for animals in research. The NIH's animal welfare policy has been revised effective January 1, 1986, to sharply tighten the conditions under which the use of animals may be approved by NIH.

The new assurance program is underway now. One thing we noticed right away in the report from the Office for Protection from Research Risk is that there are fewer assurances submitted this year than in the past. This year we got 630 assurances versus some 800 that were active last year.

Some small institutions have come in under the umbrella of larger institutions. Some that previously had two or three assurances have centralized their programs.

Senator WEICKER. What is assurances?

Dr. PICKETT. A statement of assurance that the institutions will comply with the NIH guidelines in the proper care, housing, space, air exchanges, health of the animal, that sort of thing.

AMERICAN ASSOCIATION FOR THE ACCREDITATION OF LABORATORY ANIMAL CARE

Senator WEICKER. You got fewer of these this year?

Dr. PICKETT. We got 170 fewer——

Senator WEICKER. What does that mean is going on out there?

Dr. PICKETT. Some institutions apparently are not receiving funds for activities involving animals and have chosen to no longer be included in the program. Some are in the position of upgrading their facilities to be able to provide better assurance.

The recent closure of an institution, which I am sure you are alluding to, Columbia, resulted from a careful examination of a 500-page assurance that they submitted as of January 1. There were certain factors there that did not meet our requirements and further investigation indicated that was indeed the case.

So Dr. Wyngaarden issued a letter stopping the activities there—stopping animal work above the rodent, supported by NIH grants, until such time as those conditions should be alleviated.

You see, when the people write in they have to tell us whether they are AAALAC accredited or not.

Senator WEICKER. What?

Dr. PICKETT. AAALAC, is the American Association for the Accreditation of Laboratory Animal Care. It is a national body that sends laboratory animal science trained veterinarians on site visits to assess the conditions at institutions. They examine the centralization of care, the condition of the animals, the operations of the animal care committee, et cetera.

Those that do not have this type of accreditation—and that is a great many—have to tell NIH what deficiencies they have which preclude accreditation, and how they plan to bring those conditions up to accreditable status and on what kind of a timetable.

That gives us some idea of where to look, and where to make further investigations. About one-third of the assurances, I am told, are from institutions that are presently accredited. But, unless an institution is 100 percent accredited—some of them have a number of different satellites and different areas where they have animals—we do not count the assurances as one from an AAALAC accredited institution.

Senator WEICKER. How many situations do we have here like the one at Columbia?

Dr. WYNGAARDEN. Senator, we are not sure. I think the point Dr. Pickett made about the revision of the guidelines needs a little more emphasis. We, in fact, have had animal welfare policies at the NIH for a longer time than we have had policies for the protection of human subjects.

These policies have been revised periodically, and a recent revision greatly increased the degree of specification of the report that must be filed with us, which Dr. Pickett referred to as the assurance. That is the assurance from the institution that they either are in compliance with our guidelines or, if not, what their timetable is for coming into compliance.

The degree of specificity of that report is such that we are now discovering—in fact, the institutions are discovering for themselves in much greater detail—where they are not in full compliance. I think in the current year or in a few years we will see many institutions investing more heavily in their animal care programs.

At Columbia, in the process of filling out the new assurance document, they detailed for themselves and probably discovered for the first time for themselves a great many areas of noncompliance. From this they can remedy the situation if they are willing to invest in more people and more program supervision.

They do not have structural problems. Other institutions may have structural problems where they really need to renovate facilities to come into compliance.

Senator WEICKER. That is what worried me. Let's face it, at least from a layman's point of view, you would certainly include Columbia as one of our most prestigious institutions in the United States.

Dr. WYNGAARDEN. Yes; indeed.

Senator WEICKER. If indeed they are having problems in that area I have to wonder who else is having problems.

Dr. WYNGAARDEN. Not all institutions have problems. On the other hand, we might cite the University of California at Riverside where there was a break-in a year or so ago and many hundreds of animals stolen, a great deal of property stolen and damaged, and allegations made of improper care of animals.

We sent a site visit team there, including many extramural scientists and veterinarians specialized in this field. They examined in great detail not only their facilities but also their procedures. We found that they were in total compliance with all our requirements.

IMPACT OF INDIRECT COST FREEZE ON INSTITUTIONS

Senator WEICKER. Do you think the indirect cost freeze as proposed by the administration is going to affect the institutions' ability to respond to the new animal regulations?

Dr. WYNGAARDEN. Many of the requirements of institutions to be in compliance will involve more resources, and the kind of resources that are used for those are, of course, the flexible resources in the institution including the indirect cost component.

On the other hand, if they can justify space costs, energy costs, and so forth, those that apply to the animal facilities should not be affected.

Senator WEICKER. Senator Specter?

Senator SPECTER. Thank you, Mr. Chairman. I have no questions. I would like to submit some for the record.

1987 PROPOSED REDUCTION

Senator WEICKER. One last question. You are taking a more than 10-percent cut, is that right? What is the total asked for this year?

Dr. PICKETT. $234,192,000. It is a 19.5-percent cut below the revised 1986, with the understanding that the biomedical research support formula grant has been eliminated in the 1987 request. The other programs have relatively small changes from 1986 to 1987.

RESEARCH RELATED TO RADON GAS

Senator SPECTER. Mr. Chairman, I would like to ask one question. We have had a substantial problem on the so-called Reading prong radon gas and I would be interested to know if that might be the subject of any activity from the Division of Research Resources.

Dr. PICKETT. No; it hasn't sir, to my knowledge.

Senator WEICKER. Would the head of your Environmental Division be able to respond?

Dr. WYNGAARDEN. Yes; Dr. David Rall, Director of the National Institute of Environmental Health Services.

Dr. RALL. NIEHS does not deal with radioactive material. That responsibility has been within the National Cancer Institute. It is a very serious problem. The concentration of radon in some areas—and you are absolutely right, Pennsylvania is one of the worse—is potentially serious. As we seal up our houses to make them more energy efficient, we fail to dissipate the radon.

I would be glad to supply you information, but it is not within our primary responsibility.

Senator Specter. I would be interested to have whatever you have available. It is a major problem that extends from Pennsylvania through New Jersey, New York, and even into Connecticut. It is a very hard issue to evaluate. The only studies have been conducted on miners who have an enormous amount of exposure. So it is very hard to draw any standard as to potential ill effects from the kind of exposure which is present in the so-called Reading prong.

The Environmental Protection Agency is working on it at the present time, and perhaps since it comes under the jurisdiction of the cancer group we would like to make inquiry there as well.

Thank you very much, and thank you, Mr. Chairman.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. There will be some additional questions from various Senators which we would like you to respond to for the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

BIOMEDICAL RESEARCH SUPPORT GRANT PROGRAM

Question. I have been told that the Biomedical Research Support Grant Program is one of the more important basic support programs for our institutions engaged in research. Can you give a brief description of this program and indicate why it is important?

Answer. The Biomedical Research Support (BRS) Grant Program of the Division of Research Resources is one of several federal programs designed to strengthen and enhance the research environment of institutions heavily engaged in health related research. The BRSG Program provided funding support to 557 institutions in 1985 and an estimated 575 institutions in 1986. United States health professional schools (medical, dental and nursing schools as well as schools of pharmacy, public health and others), academic institutions, research hospitals and research organizations are eligible for BRS awards.

Eligibility is based on receipt of at least 3 Public Health Service (PHS) biomedical or health-related behavioral research grants totalling at least $200,000 in the last fiscal year. Each eligible institution is granted an award based on a formula allocation of the total BRS funds.

Biomedical Research Support grants give grantee institutions the responsibility for on-site allocations of research funds. Such flexibility enables quick response to unexpected needs or a sudden change in research emphasis. Further, the BRSG can provide seed money for pilot projects that explore new theories or techniques. As research progresses, investigators may suddenly need to learn new skills, a promising project may be without funds between grants, or a new idea may merit exploration. The flexible funds of the BRSG Program complement or supplement PHS research project grants by providing for short-term, emergency, low cost, interim, and shared research resource needs.

ELIMINATION OF BRSG PROGRAM

Question. Why does the FY 1987 budget submission propose to stop the program?

Answer. In view of the growing concern for budget control, the Director of the National Institutes of Health determined that the Biomedical Research Support Grant Program, which provides generalized institutional support, must rank as a lower priority when compared to other NIH programs which permit the focusing of research funds to specific priority areas. In order to provide continued support to research investigators at those institutions most heavily engaged in biomedical research, institutions will be encouraged to require more sharing of resources and facilities, allow more release time for investigators to conduct pilot research activities, initiate institutional development programs for new investigators, and seek additional funds from within the institution and other private sources.

Question. Will loss of this program affect larger institutions in the same way as smaller institutions?

Answer. Because of the flexible nature of BRSG funds, the institutional impact of eliminating the BRSG Program will vary from institution to institution depending upon how the institution chooses to use its BRS award, whether small or large. Each Biomedical Research Support Grant eligible institution is granted an award based on a formula allocation of the total BRS funds available. The formula is calculated to give more weight to the first $200,000 of eligible Public Health Service (PHS) grant support, which results in the smaller institutions receiving a higher proportion of BRSG dollars awarded to total PHS research grant base dollars than the larger institutions. In 1985, institutions with the smallest allowable research grants base received BRSG awards of $9,957, while the largest institutions received awards of $384,384.

Question. What will be the effect on the young, newly trained scientist?

Answer. Young, newly trained biomedical researchers some of whom were formerly assisted by the BRSG, will seek funding support from other sources, both federal and private. All new investigators are eligible to apply for National Institutes of Health awards such as the First Independent Research Support and Transition Award (FIRST), research career development awards, individual fellowships, and postdoctoral traineeships under the institutional research training grants. Newly trained scientists are also eligible to submit applications for traditional research project grants.

REDUCTIONS IN THE BIOMEDICAL RESEARCH TECHNOLOGY PROGRAM

Question. The Biomedical Research Technology Program, which began in 1962, proposes to support 60 centers in FY 1987 at an approximate reduction of 10% under funding received in FY 1986. Is that correct?

Answer. No. The average size of a Biomedical Research Technology (BRT) grant in FY 1987 will increase very slightly over the 1986, post-sequestration level. In FY 1986, the post-sequestration average cost is estimated to be $559,000; in FY 1987, the President's Budget requests support for 60 BRT centers at an average estimated cost of $565,000 -- a slight increase of one percent over the FY 1986 level.

Question. What is the impact of a reduction of 10%?

Answer. The President's Budget proposes a slight increase in 1987 over the 1986 revised level.

EMPHASIS ON DEVELOPMENT OF BIOTECHNOLOGY

Question. I have read that modern technology is continuously increasing its impact on the ability to conduct research, and other countries such as Japan have become increasingly competitive in this area and threaten to outdistance us. Shouldn't we be putting greater emphasis on the development of biotechnology?

Answer. The Division of Research Resources does place a great emphasis on the development of technologies for biomedical research, primarily through its Biomedical Research Technology (BRT) Program. The BRT Program focuses on applications of knowledge engineering, information technology, biomedical engineering and digital technology for biomedical and clinical research programs, and technologies for the study of biomolecular and cellular structure and function.

In the computer area, the Program has developed a number of important resources including: expert systems for medical diagnosis and for assisting physicians with the management of patients enrolled in cancer chemotherapy protocols; computer graphics techniques for modeling molecular structures of proteins; quantitative imaging technology for analysis of three-dimensional images of organs, tissues and cells; specialized systems for diagnosing and assessing eye damage, aiding hearing, and modeling of neural processes; and the PROPHET System, a large, integrated computer system for management and analysis of research data. In the area of technologies for the study of biomolecular and cellular structure and function, the Program has developed and used mass spectrometry and nuclear magnetic resonance techniques for structure determination and analyses of biological materials; million volt electron microscopy for study of cellular structure in three dimensions and scanning transmission electron microscopy for analyzing biomacromolecules in the cell in situ.

Research accomplishments and new scientific advances made in these BRT centers have helped the United States research community to remain competitive in biomedical research technologies, particularly in the development of research and diagnostic instruments in the field of magnetic resonance imaging, and we expect to continue to make some progress under the budget request.

ADDITIONAL FUNDING FOR BIOMEDICAL RESEARCH TECHNOLOGY PROGRAM

Question. In your professional judgment, how much more than the $42 million requested in FY 1987 should be made available to our research community?

Answer. In my professional judgment, an additional $10.3 million could be effectively used for the Biomedical Research Technology Program in 1987.

Question. How would you use these additional funds?

Answer. $3.7 million of the increase would be used to restore the average 10 percent downward negotiation of all BRT centers. $0.6 million would be used to restore the one BRT center that is planned for termination in 1987. The additional $6.0 million would enable us to initiate several new BRT resource centers in the areas of supercomputers, in vivo Nuclear Magnetic Resonance spectroscopy, and new imaging methodologies, which would serve both basic and clinical research scientists and would greatly facilitate application of these powerful new tools to biomedical research problems.

SHARED INSTRUMENTATION GRANTS

Question. In 1983 NIH projected a $100 million target to replace and update essential and expensive instrumentation for the extramural laboratories engaged in biomedical research. What is the status of that program, and how much more funding will be required to keep our laboratories on the cutting edge of a rapidly developing biotechnology?

Answer. NIH has met its $100 million target to replace and update instrumentation, and has decided to continue the program to ensure core support of more state-of-the-art instrumentation in extramural laboratories. Since its inception in 1982 to the present time, the Biomedical Research Support - Shared Instrumentation Grant (SIG) Program has made a total of 540 shared instrumentation awards at a cost of $99.8 million. The SIG Program has been, and continues to be, well received by the research community as evidenced by the submission of between 200 to 250 applications per year. The mission of the SIG Program is to assure that our biomedical researchers have access to state-of-the-art sophisticated instrumentation. Instrumentation in the $100,000 to $300,000 range is an acute problem not only today, but for the future, because technological progress quickly renders instrumentation obsolete. For example, in the last three to four years, an array of new experimental methods have come into existence which have revolutionized many areas of medical science.

The Shared Instrumentation Grant Program has been helpful in alleviating the problems of acquiring complex instrumentation for both basic and clinical scientists. However, the rate at which instruments become non-state-of-the-art (approximately five to six years) has shortened their useful life. Sustained investment is required to keep institutions equipped with modern instruments.

Question. In your professional judgment, what will happen if we do not provide our research institutions with this modern instrumentation?

Answer. If we do not continue our program of providing research institutions with state-of-the-art research instrumentation, the existing equipment will become worn out or obsolete due to the rapid changes in, and the complex nature of, modern biomedical research methodologies.

In a recent survey of academic research equipment and equipment needs in university departments of biological and medical sciences, nearly 60 percent of department heads reported that there are important subject areas that cannot be addressed because of lack of necessary equipment. Department heads assessed the adequacy of the instrumentation in place in 1983 as: excellent, 16 percent; adequate, 57 percent; insufficient, 27 percent.

UNITED STATES VS. JAPAN IN DEVELOPMENT OF BIOTECHNOLOGY

Question. Can you compare where our research establishment stands in the development of biotechnology in comparison to the Japanese?

Answer. In relation to research technologies for biomedical research where significant markets exist, U.S. industry continues to compete effectively in instrument development. For example, U.S. companies are leading the world in the development of research and diagnostic instruments in the new field of magnetic resonance imaging. The U.S. position is less satisfactory in areas such as electron microscopy and mass spectroscopy with more limited instrument sales but important potential research applications in biomedical science. Companies from Europe and Japan continue to dominate the advanced instrument markets in these areas.

ANIMAL WELFARE POLICY

Question. Congress has recently developed a new animal welfare policy establishing new and more stringent requirements on the care and use of animals in biomedical research. How will these requirements affect the institutions using animals for research?

Answer. The new animal welfare policy places the following requirements on institutions using animals for research:

- More specific identification of responsible officials and administrative structure for the institutional animal care program.
- A veterinarian experienced in laboratory animal medicine must supervise the animal health care program and be a member of the institutional animal care program.
- The institutional animal care committee must have a member who is not a scientist and one who is not a member of or related to a member of the research institution's staff. They may be the same person.
- Institutions must report on their organizational structure, management system, procedures used and the size of their facilities and the size of their animal population.
- The Animal Care Committee must review and approve research protocols using animals that are part of any PHS application.
- All research institutions (grantees) must be American Association for the Accreditation of Laboratory Animal Care (AAALAC) - or self-accredited using the NIH Guide for the Care and Use of Laboratory Animals. Deficiencies must be reported together with a plan to correct them.
- The NIH Office of Protection from Research Risks (OPRR) may decide to make site visits to any grantee institution to evaluate their animal care program. Formerly, AAALAC-accredited institutions were exempt from these visits.
- The new policy provides for a waiver of a policy provision or provisions.

To the extent that institutions have not had a program that meets the criteria identified above, changes to meet these requirements will have to be implemented.

Question. How much of the additional resources required will be paid for by NIH?

Answer. NIH grant programs can provide some of the additional resources required to implement the new animal welfare policy. For example, this could include funding more user charges for investigators who use animals in their research, increased per diem rates for housing laboratory animals, and, in some cases, support for alterations and renovations and other needs.

Question. Are you requesting enough funds in the FY 1987 budget to help these institutions meet these requirements?

Answer. Funds are included in the 1987 budget request for NIH to help institutions meet some of these new animal welfare requirements. Institutions will, however, have to seek support from a variety of other sources for their animal welfare needs. The 1987 budget request for NIH research project grants proposes an average cost increase of 2 percent over the 1986 level. By combining this 2 percent increase with prudent management practices, investigators may be able to absorb some of the additional animal welfare costs.

ALTERNATIVES TO THE USE OF ANIMALS IN RESEARCH

Question. PL 99-158, which reauthorizes the National Institutes of Health, requires that you support research into alternatives to the use of animals in research. I also note that you recently published the results of a study on the use of non-mammalian research models. What are the results of this study?

Answer. An NIH-wide evaluation study resulted in a report entitled, Models for Biomedical Research: A New Perspective. The report, received in March 1985, contains several recommendations for programmatic activities and is a thoughtful analysis of modeling in biological sciences. The report reviewed, evaluated and reported on the relevance of various models for biomedical research, paying particular attention to invertebrates, nonmammalian vertebrates, in vitro techniques (cell and tissue culture), and nonbiological approaches (mathematical and computer-assisted systems). The report recommends that:

1) NIH strive to make favorable systems readily available to the research community by providing support to supply organisms for research, maintaining stock centers for mutant strains and cell lines, facilitating access to computer programs for biomedical modeling, maintaining databases like those for protein and DNA sequences, and providing long-term support for collections of monoclonal antibodies.

2) NIH consider supporting development of new model systems for specific research areas.

3) NIH consider encouraging interest in nonmammalian systems through fellowships, symposia and direct support of model developments.

4) NIH investigate the concept called "The matrix of biological knowledge" as a potential tool for biomedical research. This concept explores the interrelationships in existing biological knowledge.

Question. What steps have you taken to implement the requirements of PL 99-158 in this area?

Answer. NIH has prepared a legislative implementation plan for meeting the requirements of PL 99-158, including the design by October 1, 1986 of "a plan for research to be conducted by or through the NIH and the national research institutes into methods of biomedical research and experimentation which do not require the use of animals; which reduce the number of animals used in such research; or which produce less pain and distress in such animals than methods currently in use." Also, the planned design would include "an information clearinghouse to respond to the information dissemination directories contained in subsection (b) of the law, and the required Interagency Coordinating Committee."

Question. Have you requested funds in the FY 1987 budget to implement this requirement?

Answer. Research focused on various models in biomedical research is an NIH-wide activity which is of interest to the entire biomedical research community. Most of the NIH bureaus, institutes, and divisions are presently supporting some research on mammalian and non-mammalian animal models, in vitro systems, and computer simulations. Funds specifically for biomedical models and materials resources are requested within the 1987 budget.

AVAILABILITY OF VETERINARIANS

Question. New NIH animal welfare policies and procedures require grantees to have veterinarians who are laboratory animal specialists. Are there sufficient specialists available?

Answer. Laboratory animal veterinarians are needed to direct institutional programs of animal care and use and to solve problems of intercurrent disease in laboratory animal colonies. Currently available figures indicate that 220 trainees and fellows have completed training since the inception of the Division of Research Resources' training programs in laboratory animal science and medicine; 70 of these are employed by medical schools and 86 by other academic, research, or Governmental organizations. The majority (132) are serving as directors or staff members of a vivarium; 71 are engaged in teaching and research or are obtaining additional training; and 17 are in public health, private practice, retired, or deceased.

Since the number of specialists in the field certified by the American College of Laboratory Medicine has increased only 12% (263 to 294) in the last 5 years and many Diplomates have or will soon reach retirement age, the current number of graduates from DRR-supported training activities (12-15 per year) is inadequate to provide the manpower required by institutions to implement the new Animal Welfare Policy.

ANIMAL FACILITIES IMPROVEMENT AWARDS

Question. In FY 1985, DRR received $7.3 million for competitive grants to assist institutions in upgrading their lab

animal facilities and developing centralized programs for animal care. What happened as a result of this effort?

Answer. An announcement was made in the December 7, 1984 NIH Guide for Grants and Contracts describing the animal facilities improvement program. Institutions were allowed to request up to $500,000 for alterations and renovations (A&R) on a 50:50 matching basis plus needed equipment. A total of 100 applications were received requesting $38.6 million, including $16.2 million for equipment and $20.8 million for A&R. The latter category was matched by a $29.5 million institutional commitment. Seventy-four applications were recommended for approval with budgets totaling $20.2 million. From these 74 approved applications, 23 one-year awards were made in fiscal year 1985.

Question. How will this need be met in FY 1987?

Answer. The 1987 budget request includes $3,981,000 for continuation of the animal facilities improvement program. It is expected that this will support approximately 9 new animal facility improvement awards.

MINORITY HIGH SCHOOL STUDENT RESEARCH APPRENTICE PROGRAM

Question. You indicate that you plan to continue funding for the Minority High School Student Summer Program. How many students will you support in FY 1987 as compared to the last two years?

Answer. In 1987 we expect to support 1,000 students through the minority high school student research apprentice program, the same number as in 1985 and 1986.

Question. Can you give this committee actual examples of students who have chosen to continue their education and training?

Answer. Since the minority high school student research apprentice program began in 1980 with only 200 students participating in that first year, we do not yet have actual examples of students who have completed their education and training. We do, however, have results of a study of 1984 progress reports:

- 96 percent of the students plan to enter college.
- 68 percent of the students who plan to enter college expect to major in the biological and health sciences.
- 58 percent of the students indicated that the program had influenced them to pursue a research career, with 25% still undecided.
- 71 percent of the students selected a career in biological and health professional sciences as their future career choice.
- Four student participants in the 1984 program were honored in the prestigious Westinghouse Science Talent Search.

Question. In your professional judgment: how is this program working?

Answer. I believe this program is working very well as evidenced by the statistics presented in the previous answer. It is a relatively inexpensive program, an investment in the future of these minority students that I believe will pay off with substantial dividends to the biomedical research community.

Dr. Daniel Koshland, Editor of Science, in a recent editorial, underscored the importance of the early introduction of students to the idea of science careers.

Question. How can it be improved?

Answer. Since the program is working relatively well right now, there is not much need for improvement. One area that was suggested for improvement by participating schools was to increase the size of the high school student group at each participating institution. When students come to a school it is not a good idea to have just one or two high school students lost in a mass of students at a college. If a critical mass of three, four, or more students could be assembled at each school to invite scientific collaboration, sharing of ideas, and camaraderie among the students it could go a long way toward influencing those students toward a career in biomedical research. We have begun to do this, and note an increased number of students supported at each institution.

Question. Is the funding level adequate? If not, how much more would be necessary?

Answer. The $1,500,000 requested in the 1987 budget is adequate. It will provide support for 1,000 high school students.

SUPERCOMPUTERS

Question. I understand that the new generation of super computers have become essential tools in some of the sophisticated biomedical research endeavors. What is the Division of Research Resources doing to provide necessary access to these computers for biomedical research scientists?

Answer. In February, 1986 a joint program between the National Science Foundation (NSF) and the National Institutes of Health (NIH) was announced that will provide NIH investigators access to NSF supported supercomputers. Up to 25 hours of supercomputer time will be awarded to qualified researchers to allow them to explore the use of supercomputers in biomedical research problems. To be considered for an award investigators must submit proposals which describe the potential advantages of the supercomputer in their research. Proposals will be reviewed by an NSF panel comprised of individuals knowledgeable about the relevant research disciplines and the applications of supercomputing. The NIH has proposed a transfer of funds to NSF to allow NIH supported investigators access to NSF supercomputers.

For those investigators who have a need for supercomputer time beyond the initial 25 hours, DRR plans to initiate a program in FY 1987 that will provide supercomputer capabilities for biomedical researchers. Also DRR intends to fund a series of training workshops

for those biomedical investigators who need instruction in the use and application of supercomputers.

IMPACT OF BUDGET REDUCTION

Question. The President's budget proposal for FY 1987 reduces your budget by $69,744,000 under FY 1986 appropriated levels. Gramm-Rudman-Hollings, if triggered, could reduce your budget even further -- maybe by as much as 20 percent. I've known this would reduce the number of grants, possibly the size of grants, centers, training, etc., etc. Can you give us some idea of the impact of these reductions on the kinds of research that would be stopped or lost?

Answer. This is a difficult question to answer because of the uncertainty as to how large a sequestration reduction to expect in 1987. The President's Budget was developed within overall deficit targets that would preclude the need for sequestration in FY 1987. However, if DRR were to sustain further reductions in the range of 20 percent, all programs would be affected to some degree. As part of a careful review of various options, serious consideration would also have to be given to eliminating certain research activities.

Question. What impact might this have on the health of our citizens five and ten years down the road?

Answer. Again, it is difficult to predict what the impact of further reductions might have on the health of our citizens in the future. Biomedical research is a continual building block process. Scientific knowledge gained today from basic research will be used tomorrow by scientists in their research studies. Since we are unable to measure the 5 to 10 year impact of this investment, it is impossible to estimate the impact of a reduction at the margin of this investment.

Question. Can you discuss your contingency plans if these massive budget cuts should come to pass?

Answer. At the present time, DRR has not developed any contingency plans.

Question. If the automatic provisions of Gramm-Rudman-Hollings are triggered in FY 1987, your institute may well have its budget reduced by 20-25%. Have you prepared a contingency plan in the event Gramm-Rudman-Hollings becomes reality? If so, please send a copy of your plans to this committee.

Answer. DRR has not developed any sequestration plan for reductions below the amounts requested in the 1987 President's budget. The President's Budget was developed within overall deficit targets which would preclude the need for any sequestrations in FY 1987.

Question. If cuts of this magnitude become reality, how will they be distributed:

1. Intramural vs. Extramural programs;
2. Peer review system;
   Would number of site visits be reduced?
   Would travel to NIH to study section meetings be affected?

3. Would NIH employees have to be furloughed?
4. What major programs would have to be cut back?

Answer. As stated earlier, we have not developed a contingency plan in the event sequestration reductions are necessary in 1987. However, if DRR were to sustain further reductions amounting to 20-25 percent, all of the Division's programs would be affected to some degree, and we would give serious consideration to eliminating certain programs. Reductions of that magnitude would warrant a careful review of all programs before such decisions would be made.

Question. Please list the research programs of the highest priority that should not be cut and why.

Answer. If DRR were to sustain further cuts in 1987 as a result of the Balanced Budget and Emergency Deficit Control Act of 1985, all of the Division's programs would be affected to some degree, and serious consideration would have to be given to eliminating certain programs. A careful review of all programs would need to be conducted before such decisions would be made.

ACCREDITATION OF THE WISCONSIN PRIMATE RESEARCH CENTER

Question. You told us last year that one Regional Primate Center was not accredited. What steps have you taken over the past year to correct this problem?

Answer. The regional primate research center that was not accredited last year is the one at the University of Wisconsin. An institution-wide modernization and improvement program is presently underway in the College of Letters and Science, of which the Primate Center is a component. The center's program of animal care and use presently does meet the requirements of PHS policy for research animal welfare, but the University's improvement program will make it possible to hold all center animals in facilities that are under its direct control. The University has purchased a building adjacent to the center for $500,000 for its use, and DRR has allocated $350,000 to support alterations and equipment purchases to bring it up to accreditable standards for using and housing nonhuman primates.

Question. Has this center been accredited? If not, when do you expect that it will achieve accreditation?

Answer. The Primate Research Center at the University of Wisconsin has not yet been accredited. The University of Wisconsin has advised DRR that it will apply for accreditation by the American Association for the Accreditation of Laboratory Animal Care by September 1, 1986. By that time, a modernization and improvement program that is presently underway in the College of Letters and Science, of which the Primate Center is a component, will have proceeded to the point where AAALAC is expected to grant accreditation at least on a provisional basis.

Questions Submitted by Senator Arlen Specter

RESEARCH ADVANCES

Question. Dr. Pickett, in your prepared statement you noted several recent research advances, specifically in the areas of high blood pressure, cancer and an insulin-containing nasal spray. When do you expect the results of this research to reach the general public?

Answer. It is difficult to determine exactly when research advances will be made available to the general public. It takes a great deal of basic research, clinical trials, testing, and retesting before a new procedure, treatment, or drug therapy can be applied safely by the biomedical community. All of this takes time, and how quickly the final results are made available to the public is dependent upon both the pace at which the research and testing proceed and whether or not any problems are encountered as the study progresses. The current status of some of these advances is highlighted below.

The principal object of a study at the Johns Hopkins University GCRC is to evaluate the role of elevated blood pressure and elevated circulating levels of angiotensin II as risk factors in diabetic nephropathy. In hypertensive Type II diabetics, renal function declined more than 12 percent per year. In contrast, normotensive diabetics did not exhibit a significant rate of decline in renal function. Based upon the measured average rate of decline in renal function, it is estimated that these patients will require dialysis within about seven and one-half years, or at an average age of 64. In contrast, patients in the normal blood pressure group would appear to have adequate renal function well beyond age 85. These data provide very strong presumptive evidence that hypertension is a major risk factor for the development of progressive diabetic nephropathy. A clinical trial designed to test whether a drug which inhibits angiotensin II production is better than present therapy and can reverse renal deterioration in these patients is currently underway.

Studies on the GCRC at Boston University Hospital included a study on intranasally administered aerosolized insulin containing the surfactant laureth-9. Intranasal insulin was rapidly absorbed and effectively lowered plasma glucose in fasting diabetics. Potency depended on the insulin dose and surfactant concentration. Nasal irritation was proportional to surfactant concentration, with great variability among subjects. An outpatient feasibility study examining three months of use of intranasal aerosolized insulin before meals as a suplement to subcutaneous Ultralente insulin indicated that the aerosol was well tolerated, with glycemic control comparable to that during a subsequent three-month period of conventional subcutaneous insulin treatment. The results suggest that intranasal insulin has potential as an adjunct to subcutaneous insulin in the therapy of Type I diabetes. Problems to be solved include variations in how individuals administer the insulin, which causes considerable inter-individual variations in dose absorption, and studies of different surfactants to learn which will cause the least irritation. This technology will probably be accessible to the public in about two years.

GCRC-based experiments at the University of Minnesota indicate that the timing of administration of adriamycin and cisplatin, the two most commonly used anticancer drugs in the United States, substantially influences their toxicity. Extracorporeal and implantable programmable drug delivery systems may soon make the accurate timing of drug administration much more practical, allowing the use of clinical "chronotherapy" to optimize the therapeutic effects of these drugs and minimizing their toxicity.

Questions Submitted by Senator William Proxmire

SHARING OF RESOURCES

Question. Dr. Pickett, on the last page of your prepared statement, in discussing the administration's proposal to terminate the Biomedical Research Support Program, you state "grantee institutions will be encouraged to require more sharing of resources and facilities." Can you tell the Committee what steps you plan to take to provide that encouragement?

Answer. In light of the decision to terminate the Biomedical Research Support (BRS) Program, we plan to notify all former BRS grantees of the extensive national network of DRR research resources. We will encourage them to use these resources, perhaps via a research resource hotline which grantee institutions could call for advice as to the nearest general clinical research center, biomedical research technology center, primate research center, or laboratory animal sciences center.

SALARIES AND EXPENSES

Question. Dr. Pickett, last year's justifications indicated that your projected average ES salary in 1986 would be $62,920 while your average GS salary would be $26,813. Your current re-estimate for 1986 shows a substantial increase in your original estimate to an average ES salary of $66,232 and an average GS salary of $28,224.

Despite this increase and a slight rise in your original estimate of total compensable work years, your 1986 personnel compensation costs have dropped from an original estimate of $3,468,000 to a current estimate of $3,420,000.

Can you tell us how you have been able to cut these costs when the size of your staff and your average salaries have increased?

Answer. The explanation for this is that the Division of Research Resources has been given the responsibility for administering the Research Centers at Minority Institutions Program, a new program initiated in 1985 with funds appropriated to the Office of the Director, NIH. Although the funds for this activity are included in the Office of the Director's appropriation, the 2 full time equivalent positions needed to manage this program are provided by DRR and as such, they are charged against DRR's full-time-equivalent personnel count. When last year's Congressional Justification was prepared the RCMI program was in the early planning stages and we did not know the DRR would be charged for the FTE ceiling on these two positions. As a result the 98 compensable work

years reported were in support of DRR's regular programs. This year's justification reflects a total of 99 compensable work years; however, two of these are for the RCMI activity for which the salary costs are not paid by DRR. Thus, the number of work years for which DRR is paying for, and the number that is comparable to last year's justification is 97. This is a decrease of one full time equivalent from last year's justification. Since the number of compensable work years has actually been reduced by one, the reduction in the personnel compensation costs from $3,468,000 to $3,420,000 is appropriate.

In addition, we have tried whenever possible to fill vacated positions with lower graded employees, which when combined with lapse time between filling vacancies has led to substantial reductions in our personnel compensation costs.

NATIONAL INSTITUTE OF DENTAL RESEARCH

STATEMENT OF DR. HARALD LÖE, DIRECTOR

ACCOMPANIED BY:

DR. JAMES WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

GILBERT D. PRESS, BUDGET OFFICER, NATIONAL INSTITUTE OF DENTAL RESEARCH

DENNIS P. WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTRODUCTION OF ASSOCIATE

Senator WEICKER. Our next witness will be our good friend Dr. Harald Löe, Director of the National Institute of Dental Research. Dr. Löe, please introduce your colleagues and proceed in any way you care to.

Dr. LÖE. Mr. Chairman, with me here today is Mr. Gilbert Press who is the budget officer in the Institute.

I would like to submit my written statement for the record, but I would also like to make three or four points that relate to NIDR activities over the past year. They concern specific advances coming from cell and molecular biology, new initiatives in AIDS research and in aging, and expanded science transfer activities.

One important feature of molecular techniques is that they are allowing us to move more quickly from basic knowledge to clinical application. A case in point is the work that our salivary gland researchers have been able to do to define critical cell surface receptors and demonstrate the mechanisms by which water and salt are imported into salivary gland cells, processed, and then exported as saliva.

These studies have led to new treatments of a syndrome we call dry mouth, a condition that affects millions of Americans, either because of primary disease, or as a side effect of more than 400 over-the-counter or prescription drugs.

In bone research we can now sample bone-forming cells from healthy people and from patients with osteoporosis, osteoarthritis, or any other bone disease, culture them in a laboratory dish, and watch the cells' behavior over periods of weeks and months as a clue to the pathology.

We have also isolated and purified a small protein that we call osteogenin, believed to be an active factor in the formation of new bone following bone fracture or bone loss.

Genetic engineering technology was also the principle applied in the development of the herpes vaccine that I reported on last year. Further work on the vaccine has established that mice vaccinated last year are still protected when challenged with lethal doses of herpes virus.

Our final example of progress at the molecular level is truly novel. It concerns the discovery of the active ingredient of the glue that a marine animal, the common mussel, uses to stick to rocks and to the keel of ships.

The significance of this glue is that it works in salt water, where no man-made adhesive has ever worked before. We have supported a grantee in Connecticut who has been able to single out the key protein in this substance. Now there are plans to manufacture this glue through genetic engineering for widespread applications as a sealant and a filling material in dentistry, as an aid in muscle, tendon, and bone attachment in orthopedics, and, by a slight change in the formula, as a coating of ship bottoms to prevent the attachment of marine animals.

This year the NIDR is also expanding its research on AIDS, as more and more information is accumulating that oral opportunistic infections play an important role in the natural history of this disease. We have made important immunological findings and are moving on to an analysis of changes in the oral tissues and oral fluids.

There are major steps to improve oral health in the aging population. Later this year we will be announcing preliminary results of the most comprehensive oral health survey ever conducted in America. The survey will provide up-to-date documentation on the extent and severity of various types of tooth decay, periodontal diseases, and other oral conditions in adults, based on an examination of 20,000 Americans in the workplaces and in centers for the elderly around the country. We are encouraging the profession and the research community to address the needs of older Americans, and we will be releasing next week at a major dental research meeting here in Washington, a new research agenda on oral health in the elderly developed jointly by the NIDR, the National Institute on Aging, and the Veterans' Administration.

More and more we are emphasizing the importance of science information and technology transfer to promote the adoption by the public and the profession of the newest preventive and treatment regimens.

We began to get the message across with the early work on fluorides. The process has continued with the demonstration of the effectiveness of dental sealants. Now science transfer activities extend to research on the risks of using smokeless tobacco, smoking during pregnancy, and many other areas where we are concerned to reduce the risk of disease and to promote oral and general health.

The fiscal year 1987 budget for the NIDR is $96,482,000, and I will be pleased, Mr. Chairman, to answer any questions that you may have.

ANTICARIES VACCINE

Senator WEICKER. Thank you very much, Dr. Löe.

Where do you stand on the anticaries vaccine?

Dr. LÖE. We are continuing our work on the anticaries vaccine. There are activities in purifying and testing candidate antigens, and in monitoring and assessing the immune response to these antigens. The research is complicated because there are three different immune systems that can operate in the oral cavity: cellular immunity, humoral immunity, and secretory immunity.

All three of these systems may take part in the host reaction to tooth decay-causing bacteria. However, the one that may be closest to being utilized is the secretory response in which antibodies are released in saliva as part of salivary gland activity.

We continue to explore research issues in animal models. There also are some studies in human volunteers to assess antibody titers raised to some of the antigens. The research is progressing in an orderly manner and at this time we see no reason to accelerate activities in this area.

It is well known that we are seeing a dramatic decline in tooth decay in this country. This was documented in our studies in 1979 and 1980. There are new data from various parts of the country which indicate that this level is holding, and perhaps even improving.

So it may well be that a caries vaccine is not going to be needed in this country. However, there is a whole world out there. The developing countries are seeing an enormous increase in tooth decay and a vaccine may be more important to them than it would be for our own population.

In any case, there is much to be learned from research in this area; much that needs to be known about fundamental host responses and about immune responses in the mouth and in related tissues. I feel this investment is giving us much needed information which may one day lead to a vaccine. Such a vaccine might also be used in this country, if, for one reason or another, we cannot maintain existing fluoride programs in the future.

ANTIPLAQUE AGENTS

Senator WEICKER. Haven't I heard of the commercial development of some sort of mouthwash which is intended also to assist in this process vis-a-vis placque, or something like that?

Dr. LÖE. That is correct. There has been a lot of media exposure.

Senator WEICKER. Is this a valid discovery?

Dr. LÖE. Yes, Mr. Chairman; this is not just another advertising gimmick. There is a rationale for the use of antimicrobial agents in the control of tooth decay and in periodontal diseases. Both of these diseases are caused by bacteria, and the use of antimicrobials to control or prevent the growth of these bacteria seems a reasonable approach.

HERPES VACCINE

Senator WEICKER. Where do you sit on your herpes vaccine? What are the results on that?

Dr. LÖE. We are still doing animal research on the herpes vaccine. First of all, as I reported in the opening remarks, it is important to test the duration of the effect of the vaccination. We now have evidence that the mice continue to be protected after 12 months.

We are also conducting research to determine the need and value of booster injections in order to maintain the level of the antibody reaction. We are not ready to move into the human model as yet.

There is another interesting development in terms of the antigen chosen. I reported last year that we are using a gene for a specific protein from the cell surface of the virus and that the gene is incorporated into vaccinia virus as the vehicle.

One of our extramural grantees has been able to break down this protein to smaller units, and the amino acids that make up this protein have been characterized. It is possible that this approach will lead to the production of a synthetic antigen, and that we will be able to circumvent some of the problems related to the use of the vaccinia virus. I find this a very encouraging development in our efforts to produce a vaccine that is efficacious and safe.

AIDS RESEARCH

Senator WEICKER. Has your Institute been involved with the questions arising from the AIDS problem as to the oral transmission of the virus, kissing, et cetera, are you looking into this matter?

Dr. LÖE. Yes; we are interested in it, of course. This is our area of expertise—not necessarily kissing, but the mouth.

Senator WEICKER. You are speaking as Director of the Institute and not as an individual. [Laughter.]

Dr. LÖE. Right. I think it is probable that AIDS is not transmitted through saliva. I am not saying that it can't happen, but I think the possibility is unlikely. However, there is documentation of the presence of the virus in saliva and we need to study that in more detail. For one thing, we must make clear what is meant by saliva and by oral fluids. Saliva is a product of salivary glands, but after it is secreted in the mouth it mixes with bacteria and with other substances in the mouth.

If you have periodontal disease, for example, your gums may bleed and saliva will be contaminated by the blood. Under these conditions, if the AIDS virus is in the bloodsteam, it could show up in a sample of saliva: clearly we need careful studies in this area to document what is happening in the oral cavity and, as I said, this is one of the areas which we are now exploring.

PREPARED STATEMENT AND QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Dr. Löe, I thank you very much. There will be further questions that I know the committee will want to have responded to for the record.

Are we going to set up an appointment, Jim, with your press staff?

Dr. Wyngaarden. Yes; he is on schedule I think for Wednesday morning.

[The information follows:]

Statement of Dr. Harald Löe

Each year it has been my pleasure to describe current Institute accomplishments and initiatives and put them into the perspective of our Long-Range Research Plan FY 1985-1989, Challenges for the Eighties, published in 1983. In the Plan we affirmed the continued need to emphasize basic research as a key to understanding the oral tissues and their problems. To underscore that commitment we observed that dental investigators were quick to adopt the new techniques of cell and molecular biology, in particular, recombinant DNA and monoclonal antibody methods, to attack long-standing problems.

It is gratifying to report now how rapidly this "molecularization" of biology is transforming dental research. Moreover, the new technology is achieving another Institute goal stated in the Plan: accelerating the movement of laboratory findings to clinical applications.

This year we saw major gains in mineralized tissue research. Earlier studies of bones and teeth have paid off in important discoveries concerning collagen, tooth enamel, and the cells and extracellular factors that regulate the growth, maintenance and repair of mineralized tissues. Now, for the first time, NIDR scientists have perfected cell culture techniques that are permitting long-term studies of the behavior of normal and diseased bone cells in a laboratory dish. The scientists are studying cells from patients with all kinds of bone disease, from the hereditary "brittle bone" diseases like osteogenesis imperfecta, to the crippling diseases that affect so many older Americans--osteoarthritis and osteoporosis.

These same investigators have also cloned the genes that code for two important proteins involved in bone metabolism. Monoclonal antibodies have been raised to these proteins and the investigators are using the antibodies and other probes to compare osteoporotic bone tissue with normal tissue in search of clues to the pathologic process.

Another exciting development has been the isolation and purification of a small protein, called osteogenin, believed to be an active factor inducing new bone formation following bone fracture or loss. Plans now call for an NIDR-industry collaborative effort to characterize the protein fully, with the hope of using recombinant DNA methodology to produce osteogenin in quantity for use in reconstructive surgery.

Studies of saliva are another area where dental investigators have long had a claim to fame, demonstrating the many ways in which saliva works to preserve and protect the oral tissues. This year NIDR investigators solved the puzzle of how water and salt are taken up by salivary cells and how the fluid, along with other ingredients, is later secreted in the form of saliva. These discoveries have led to new classifications of patients who suffer the painful symptoms of dry mouth, a condition that predisposes to a variety of oral infections, including tooth decay and gum disease. These individuals represent a surprisingly large group that includes people with specific glandular and rheumatological disorders, patients who have undergone radiation and chemotherapy

for cancer, and many adults who take daily medications with a side effect of oral dryness. Tests developed by the NIDR scientists now show that in some of these people the salivary cells are still able to take up salt and water but are blocked in secreting the end product, saliva. That observation has led to the experimental use of the drug pilocarpine which has proven to be a safe and effective means of unblocking the secretory channels and restoring the flow of saliva.

A third example of the molecular revolution in dental research concerns vaccine development. Last year we reported the success of a genetically engineered vaccine against herpes simplex virus type 1 (HSV 1), the cause of the oral lesions called cold sores. The vaccine, composed of the vaccinia virus and a gene coding for a surface antigen of the herpes virus, provided immunity to infection by HSV 1 in mice, as well as substantial protection against HSV 2, the cause of genital herpes. Further, the vaccine protected against latent infection in the majority of cases. Now, one year later, the scientists have shown that the vaccine continues to provide immunity in the animals. This is the first demonstration of the duration of effectiveness of a recombinant vaccine and gives further impetus to animal testing in anticipation of human trials.

The Institute also continues to support work on an anti-caries vaccine. The ability to use genetic engineering methods to isolate and purify potential immunizing molecules from Streptococcus mutans, the bacteria considered the principal cause of dental caries, has increased activity in this area. This research has also attracted nondental investigators to the study of dental caries as a model of an infectious disease that can shed light on little-understood aspects of host-pathogen interactions. One such aspect concerns "secretory" immunity, a host defense mechanism in which disease-fighting antibodies are incorporated into the saliva that is secreted in the oral cavity. Several researchers have also suggested a new biotechnology approach to caries prevention. They propose that monoclonal antibodies targeted to S. mutans antigens be produced and then applied locally in the mouth to provide passive immunity to dental caries.

Oral infections have taken on special significance in dental research with the advent of acquired immune deficiency syndrome (AIDS). NIDR grantees have found growing evidence that the oral cavity is a frequent site of the serious opportunistic infections and of the Kaposi´s sarcoma associated with AIDS. Moreover, the need to treat oral conditions in AIDS patients and to adopt measures to ensure that both dental personnel and the general public are protected against exposure to the AIDS virus has been imperative.

Several NIDR-supported investigators have now identified specific oral lesions that may precede the frank clinical picture of AIDS. Changes in salivary components may occur even earlier. For example, a family of proteins normally present in saliva is known to inhibit the growth of the fungus that causes candidiasis. Clinical experience with AIDS suggests that if candidiasis develops in individuals at risk for AIDS, it is highly likely that these individuals will go on to develop AIDS.

NIDR will expand research on AIDS, building on these observations. Researchers will document the sequential development

of oral changes in relation to the natural history of the disease. Important aims will be to develop early diagnostic or predictive markers and to provide treatments and counselling for affected individuals. Treatment strategies can make use of earlier NIDR discoveries that monocytes are damaged by the AIDS virus and may even harbor the virus. They are not killed by the virus, however. Thus researchers will seek ways to eliminate the virus and restore the immune capacity of the cells.

Additional research plans include tracking when and in what quantities the AIDS virus appears in oral fluids; noting what changes may occur in the oral flora in the course of development of AIDS, and what microorganisms may be associated with opportunistic infections or malignancies. Other research will include studies of the invasiveness of Kaposi sarcoma cells and a focus on aberrant changes in another class of immune cells, the B lymphocytes. Clinical studies will include research and treatment for chronic pain experienced by some AIDS patients which is associated with nervous system damage.

The ability of the Institute to respond quickly to a sudden health emergency such as AIDS reflects the solid core of talent in the basic and clinical disciplines represented by NIDR intramural and extramural scientists. In our Long-Range Plan we foresaw the need to ensure that we maintain that base as well as build even closer ties between basic research and the clinical sciences in dentistry. Accordingly, the NIDR has developed a unique career development program--the Dentist-Scientist Award--designed for individuals with the DDS or DMD degree who wish to pursue careers in research. The 5-year program has been very warmly received by the research community and by year's end we expect to have 52 candidates enrolled in individual and institutional award programs, as well as in a comparable Physician-Scientist Award program.

Toward the same goal of enriching the talent pool and facilitating research advances, the NIDR has employed center grants, establishing 5 Dental Research Institutes some 20 years ago, and later, creating categorical research centers. In response to a request from the Committee, the NIDR has now reviewed its use of these large grant mechanisms and reported its plans to Congress. This review engaged a broad segment of the dental community, led by a 20-member advisory panel representing the major professional organizations and NIDR advisory bodies. The NIDR is in agreement with the recommendations of the panel which, in essence, advise the Institute to use all existing NIH funding mechanisms, ranging from individual investigator-initiated grants to program projects and both categorical and non-categorical center grants; to strive for balance in the research portfolio, and to ensure that all large grants are awarded through open competition and rigorous peer review. Accordingly, the NIDR has now issued a request for applications for new Research Centers in Oral Biology (RCOBs), where multidisciplinary teams can address a variety of research issues. The first awards in this program will be made in FY 1987.

Periodontal disease research is benefiting from a concentrated study of relatively rare diseases that affect young people: juvenile periodontitis and prepubertal periodontitis. Both diseases appear to involve specific inherited defects in a critical host defense cell, the polymorphonuclear (PMN) white blood cell.

These studies have given rise to a 5 site collaborative clinical study to elucidate the mode of inheritance as well as research aimed at identifying individuals at risk.

Commercial interest and involvement in preventing periodontal diseases through the use of antibacterial mouth rinses and other oral hygiene products is mounting. Some of these products are awaiting approved by Federal regulatory agencies for prescription use and should be available imminently. The new agents will be of considerable value in reducing accumulations of bacterial plaque above the gumline and hence in preventing and treating gingivitis. Since more advanced cases of periodontal disease are preceded by gingivitis, prevention of gingivitis may significantly reduce the incidence of advanced periodontal disease.

The NIDR remains committed to achieving even greater reductions in dental caries than have already been observed. We have commented that the emphasis must now be put on tailoring prevention and treatment to individuals at risk of developing decay, such as handicapped or immunocompromised patients. The NIDR plans a 1987 follow-up of its nationwide survey of school children conducted in 1979-80 to determine if caries reductions are being maintained.

Other important areas of caries research concern root caries, a form of decay that affects the exposed roots of teeth, a problem associated with gum recession in older individuals. The NIDR has been concerned about the extent and severity of this problem as well as the prevalence of secondary caries (decay around existing restorations) and of the periodontal diseases in adults and in the elderly. These concerns led the NIDR to undertake a survey of 20,000 adults and of the elderly last year. The examinations have now been completed and by the end of this year we expect to have the data in hand that will give us a significant baseline by which to judge the oral health status of working adults and non-institutionalized elderly.

This information is vital to the NIDR as it turns toward the challenge of preserving the human dentition for a lifetime. We have combined forces with the National Institute on Aging and the Veterans Administration to define a Research Agenda on Oral Health in the Elderly. That agenda will form the basis for joint research projects and announcements to the research community and to the public of our interest in fostering research in the area. One aspect that we are highlighting is the need for research on methods of oral health promotion and disease prevention appropriate for older groups.

Prevention is just not for children any more. Substantial reductions in the oral health problems seen in aging can be achieved by adopting a lifelong program of prevention. Ideally one begins in infancy, but those who start later in life, even at 50 plus, can reap enormous benefits from preventive regimens. Dental research has established that prevention works. Adults can and should act now to secure the healthy future they desire and deserve.

The budget request for FY 1987 is $96,482,000. I will be happy to answer any questions.

Biography of Dr. Harald Löe

July 19, 1926, Steinkjer, Norway

Education: Oslo University, Norway, D.D.S., 1952; Dr. Odont, 1961.

Professional History: 1952-1955, Instructor in Operative Dentistry, School of Dentistry, Oslo University, Oslo. 1956-1962, Research Associate, Norwegian Institute for Dental Research, Oslo. 1957-1958, Fulbright Research Fellow and Research Associate, Department of Oral Pathology, University of Illinois, Chicago. 1959-1962, University Research Fellow, Oslo University, Oslo. 1960-1962, Associate Professor, Department of Periodontology, School of Dentistry, Oslo University, Oslo. 1966-1967, Visiting Professor of Periodontics, Hebrew University, Jerusalem. 1962-1972, Professor of Dentistry and Chairman, Department of Periodontology, Royal Dental College, Aarhus. 1971-1972, Associate Dean and Dean-elect, Royal Dental College, Aarhus. 1972-1974, Professor of Dentistry and Director of the Dental Research Institute, University of Michigan, Ann Arbor. 1974-1982, Dean and Professor of Periodontology, School of Dental Medicine, University of Connecticut, Farmington.

Professional Organizations: American Dental Association; American Association for the Advancement of Science; International Association for Dental Research, American Association for Dental Research; American Academy of Periodontology; Commission on Oral Health Research and Epidemiology, Federation Dentaire Internationale; World Health Organization's Oral Research Advisory Group; American College of Dentists, International Association for Dental Research Periodontal Research Group; American Association for Dental Research Periodontal Research Chapter; International College of Dentists; Danish Dental Association; Scandinavian Association for Dental Research; Sigma Xi, The Scientific Research Society.

Honors, Awards: honorary doctorate degrees from the University of Gothenburg, Sweden, 1973; the Royal Dental College, Denmark, 1980; University of Athens, Greece, 1980; the Catholic University of Leuven, Belgium, 1980; Georgetown University School of Dentistry, Washington, 1983; the University of Lund, Sweden, 1983; and the University of Bergen, Norway, 1985; Alfred C. Fones Medal for Outstanding Achievement in the Service of Humanity, 1984; International Award of the Friends of the University of Connecticut School of Dental Medicine, 1983; Lister Hill Memorial Lecturer, University of Alabama, 1983; Daniel F. Lynch Award, Dental Society of Greater Waterbury, 1983; International Lecturer of the Year Award, Academy of International Dental Studies, 1983; Gold Medal, University of Ghent, 1982; Centennial Award, University of California School of Dentistry, 1982; Award of Merit, Hartford Dental Society, 1982; Irving Glickman Memorial Lecture, Tufts University, 1979; William J. Gies Award, American Academy of Periodontology, 1978; Arthur Merritt Memorial Lecturer, Baylor University, 1977; Certificate of Achievement, Connecticut Society of Periodontists, 1976; Massachusetts Dental Society International Award, 1973; honored by Her Majesty the Queen of Denmark (Knight of Danebrog), 1972; American Society of Preventive Dentistry International Award, 1972; International Association for Dental Research Award for Basic Research in Periodontics, 1969; Aalborg Dental Society Prize of Honour, 1969; Erik Berg Foundation Prize of Honor, 1965; Ingv. Stokke Prize for Outstanding Dental Research, 1959; Norwegian Dental Association 75th Anniversary Prize, 1959; honorary memberships in several professional societies.

Questions Submitted by the Subcommittee

IMPACT OF BUDGET REDUCTIONS

Question. The President's Budget proposal for FY 1987 reduces your budget by $6,116,000 under FY 1986 appropriated levels. Gramm-Rudman-Hollings, if triggered, could reduce your budget even further, maybe by as much as 20 percent. I've known this would reduce the number of grants, possibly the size of grants, Centers, training, etc. Can you give us some idea of the impact of these reductions on the kinds of research that would be stopped or lost?

Answer. The President's Budget was developed within overall deficit targets that would preclude the need for sequestration in 1987. If additional reductions as high as 20 percent below the request were required all NIDR programs would probably be affected to some extent.

Question. What impact might this have on the health of our citizens five to ten years down the road?

Answer. It is difficult to know what the long term impact of such a reduction would be. The levels you refer to would certainly limit our ability to sustain our research base and pursue research leads.

Question. Can you discuss your contingency plans if these massive budget cuts should come to pass?

Answer. At this time the NIDR has no detailed contingency plan. However, we will continue to be objective in dealing with any reductions in the budget; that is, the Institute will try to keep the research portfolio as balanced as possible.

ANTI-CARIES VACCINE

Question. Last year you indicated that a vaccine against tooth decay was approaching the testing stage. What is the status of the development of this anti-caries vaccine?

Answer. We are continuing to seek out the most effective immunogen(s) and are testing them for cross-reactivity with human tissue. Ideally, the immunogen of choice should be produced by methods that will ensure the purity of the product--such as those of biotechnology. At a meeting to review caries vaccine research in January 1986, a distinguished group of investigators recommended proceeding cautiously, building up a body of data from animal studies looking at vaccine dosages, antibody classes, duration of response, levels of cariogenic bacteria in the mouth, and so on. Because the prevalence of caries has been declining and the disease is not life-threatening, the NIDR agrees with the conclusions of the experts that there is no urgent need to move on to clinical trials. In the meantime, much can be learned about oral ecology and the immune responses unique to the oral cavity.

These conclusions were discussed and endorsed by the National Advisory Dental Research Council.

Question. Have you been able to provide sufficient funding for a maximum research effort?

Answer. At present we have sufficient funds for conducting the level of research we feel is appropriate for caries vaccine research.

Question. Are you requesting enough funds for FY 1987 to continue this work and if not, how much more will be necessary?

Answer. The level of funding for caries vaccine research may be lower in FY 1987 than in FY 1986, consistent with the reductions in the President's budget proposal. However, much of the vaccine research is conducted by extramural scientists through competitive investigator-initiated research grant mechanisms. Because the quality of this research has been outstanding, it may be possible to maintain the same level of support in FY 1987 as in 1986.

Question. How much money would be saved if our entire population received the vaccine?

Answer. There are too many uncertainties to be able to estimate savings from a caries vaccine. To begin with, we have assumed that the vaccine would not be given to the entire population, but to very young children prior to the eruption of the first teeth. These children would then be protected against caries and hence from the cost of restorative treatment or of other means of caries prevention for as long as the vaccine is effective. We do not know how effective a caries vaccine would be if given to older children or to adults who have already been exposed to cariogenic organisms. Nor do we know if the vaccine could be effective against other forms of dental caries such as caries developing around existing restorations (secondary caries) or in protecting against root caries (which may involve different microorganisms).

HERPES VACCINE

Question. What is the status of the development of the anti-herpes vaccine?

Answer. Last year we reported on a genetically engineered vaccine for herpes simplex virus type 1 (HSV-1) which was a vaccinia virus recombinant expressing the gene for glycoprotein D of HSV-1. The vaccine protected mice against lethal challenge with both HSV-1 and HSV-2 and showed considerable protection against the development of a latent infection with HSV-1. We have now verified that mice immunized last year are still protected against HSV infection and are continuing studies of the duration of effectiveness and the effects of booster shots. Studies in human subjects are anticipated, pending the completion of animal studies and the resolution of safety issues regarding reintroduction of vaccinia virus as a vaccine.

Also, an NIDR grantee has developed a synthetic form of a small portion of the glycoprotein D which may be an effective immunogen in itself, not requiring the use of the vaccinia virus as a vehicle.

Question. Has the funding been adequate to allow for maximum effort in the development of the vaccine?

Answer. The funding has been adequate for these preliminary experiments.

Question. How many people would be helped by this vaccine, and how much money would be saved?

Answer. The vaccine would be effective only in protecting against initial infection with HSV and would not help those already infected. A vaccine against HSV would be given to pre-school age children to protect against initial infection with HSV-1. It is posible that a vaccine could be developed which would protect against infection with both HSV-1 (commonly associated with oral herpes) and HSV-2 (commonly associated with genital herpes). How effective this would be and how long the protection from one vaccination would last will not be known until clinical trials in human subjects are undertaken. The cost of the burden of HSV disease as estimated in the National Academy of Sciences Institute of Medicine Report on the Development of Vaccines follows:

	Millions
Primary genital, labial and ocular HSV	$136
Recurrent genital, labial and ocular HSV	107
Hospitalization: encephalitis, neonatal HSV, disseminated HSV	87
CNS impairment and blindness	100
HSV during pregnancy	22
Total yearly cost	$452

Question. Will the vaccine be effective on the unfortunate person who has already contracted herpes? If not, how much more should be spent?

Answer. No. We expect that the vaccine would have no effect on the frequency or severity of recurrences in patients already infected.

Question. What kind of research are you supporting to find an effective treatment for herpes?

Answer. We are conducting a series of clinical trials both intra- and extramurally aimed at identifying factors which trigger reactivation of HSV, determining the mechanisms involved in the reactivation process, and testing agents, such as acyclovir, which may block reactivation. We are utilizing a human model in which reactivation of HSV occurs in response to exposure to ultraviolet light. This model was developed by NIDR intramural

scientists in collaboration with investigators from the National Institute of Allergy and Infectious Diseases. We also want to test the accuracy of this model in predicting the clinical efficacy of antiviral agents in treating or preventing HSV reactivation.

In addition, we are initiating a clinical study of acyclovir for the suppression of recurrences in patients who suffer frequent herpes labialis (cold sores) infections.

Question. Are the funds for this effort adequate, and if not, how much more should be spent?

Answer. The funds have been adequate. However, to move this research on to clinical studies will require additional support of approximately $250,000.

PERIODONTAL DISEASE

Question. I understand that because better prevention and improved dental care are allowing our citizens to enjoy better dental health and to keep their natural teeth longer, periodontal disease is becoming a major problem. What is the status of the study you are conducting on periodontal disease, and what are the expected results?

Answer. There are several major studies of periodontal diseases under way in addition to the research conducted at NIDR's Periodontal Disease Research Centers and by individual grantees. These studies include:

-The NIDR National Adult Oral Health Status Survey of 1985-1986. Oral examinations have been conducted on 20,000 adults and older persons seen at workplaces and centers for the elderly. The examiners are documenting the extent and severity of coronal and root caries, periodontal diseases, calculus and loss of periodontal attachment. Preliminary results are expected in fall, 1986.

-Two university contracts to conduct "Clinical Studies of Periodontal Diseases in Older Adults" (ages 55-74). The major objective is to characterize which factors discriminate among older adults with and without periodontal destruction. A common protocol includes clinical, radiographic and diagnostic procedures developed by the contractors and project staff at the NIDR. The clinical phase of the study will begin in FY 1987.

-A contract study entitled the "Clinical Effect of Toothbrushing with 0.4% Stannous Fluoride Gel on Periodontal Health." The Investigative New Drug application submitted to the Food and Drug Administration for the use of the test and placebo agents has been approved, the potency of the stannous fluoride in the test has been independently confirmed, and the clinical trial was initiated in January 1986. Approximately 550 adults (ages 18 to 30), randomly divided into three groups, are toothbrushing twice a day with an American Dental Association-approved fluoride dentifrice, followed by a toothbrush application of a 0.4%

stannous fluoride gel or by a placebo gel. The study will run for 18 months with interim examinations at 6-month intervals.

-An epidemiologic survey of oral health in school children. This study will be implemented in FY 1986 to survey the prevalence of specified oral diseases in school children throughout the United States and Hawaii. Examinations will be conducted for periodontal destruction, gingival and soft tissue lesions, in addition to dental caries, treatment needs, and fluorosis.

Question. How much money are you spending on periodontal research and how does that compare to the cost of this disease to the national economy?

Answer. In FY 1985 the NIDR spent 27% of its budget or $27.7 million on research related to periodontal diseases. Approximately $4 million of these funds supports five clinical periodontal disease research centers. The NIDR, however, makes use of all support mechanisms, including career development and research training awards as well as Small Business Innovative Research (SBIR) grants in its all-out effort to conquer these diseases. Data on the cost on periodontal diseases are not readily available. Best estimates are that about 5 percent of total dental expenditures, or about $1 billion, are spent for periodontal services. It should be noted, however, that expenditures for treatment do not reflect the extent of the periodontal disease problem in the public at large.

Question. There is a substantial advertising campaign for toothpaste designed to control plaque. In your professional judgment, is this new toothpaste effective in controlling plaque and preventing periodontal disease?

Answer. Plaque control can be achieved with appropriate mechanical oral hygiene methods. Most dentrifices available today improve the efficiency of mechanical plaque removal by providing abrasive agents. Most dentifrices also contain fluoride which confers a variety of benefits. Some new dentifrices contain agents that help to soften calculus, the hardened deposits of plaque on teeth. What matters most in preventing periodontal disease is that toothbrushing be performed efficiently and that plaque is removed from all areas above the gumline where it accumulates, including areas that are not easily reached by the toothbrush, such as spaces between the teeth.

PREVENTION

Question. This Committee has supported dental research in the areas of prevention of oral disease, and has received with pleasure your reports of the success of this research. Have you conducted any studies to prove the effectiveness of preventive dentistry in reducing dental disease?

Answer. The NIDR has conducted numerous studies investigating the effectiveness of caries-preventive measures. These have included the full range of fluoride-containing

modalities: community water fluoridation (estimated to reduce caries by between 50 and 65 percent); school water fluoridation (achieving caries reductions of 40 percent); the use of fluoride tablets (reductions between 25 and 40 percent) and fluoride dentifrices (between 20 and 30 percent reductions in caries). In addition, clinical studies have shown the effectiveness of dental sealants in preventing decay on the rough surfaces of children's teeth (achieving 90 percent effectiveness in preventing decay in the first year of placement). More recently, the effects of combined caries-preventive measures have been under investigation. Meanwhile, the NIDR continues to support studies to improve existing fluoride and dental sealant modalities to increase their effectiveness.

With respect to the prevention of the periodontal diseases, the NIDR has several clinical studies under way to investigate the effectiveness of antiplaque and antimicrobial agents in the prevention of gingivitis.

SMALL BUSINESS PROGRAM

Question. The Small Business program offers the NIH the opportunity to use the talents and the ideas of small commercial firms to do research and to help transfer the benefits of research to the American public. What use has the NIDR been able to make of this program? Do any of the NIDR's small business projects have the potential to be commercially successful?

Answer. NIDR has supported a number of Small Business Innovation Research (SBIR) projects, including the development of new tools and materials to be used in clinical research and practice, as well as studies to devise anti-herpes agents. One of the most promising endeavors involves the development of a highly innovative new probe to assess periodontal disease by measuring pocket depth and attachment loss. Now in the Phase II stage of development, this project has excellent potential for commercial success.

Another SBIR project is an excellent example of how basic dental research can lead to technological innovation. A company has now been formed to market a superglue that promises to have widespread applications in dentistry, in medicine, and in shipbuilding and maintenance.

This development is the result of 10 years of basic research funded by the NIDR at the University of Connecticut Health Center to learn more about the extraordinary glue that marine animals--common mussels--produce that enables them to adhere to structures underwater. Most adhesives need dry surfaces to be effective. The mussel's glue works in a wet, saline environment as well as a dry one.

The main ingredient in the mussel glue has now been identified and plans call for reproducing the adhesive in quantity. Dentists foresee using the glue as a sealant, as a material for filling cavities, and as an adhesive for bonding teeth. Surgeons are interested because the glue could be used in operations to coat sutured tissue to prevent infection. The

adhesive could also hold together small broken bones or tendons. The Navy hopes to use the substance to coat the hulls of ships to prevent fouling by marine growth and corrosion. The glue could also be used to repair ships underwater to avoid the expense of drydocking. In August, 1985 the NIDR awarded a company a Small Business Innovative Research Grant. Recently, government approval for a patent on the composition of the basic structure of the protein isolated from the mussel glue was granted to the University of Connecticut, giving the company exclusive rights to this adhesive. Within about two years, it is expected that the adhesive will be available for topical use in dentistry. The company is also making plans to produce the adhesive in large quantities for industrial use through genetic engineering techniques.

FLUORIDE

Question. The Environmental Protection Agency has recommended doubling the amount of fluoride in our drinking water. I understand that fluoride has been effective in preventing cavities. However: Will doubling the amount of fluoride actually double the protection?

Answer. It must be clearly understood that the EPA is not recommending the doubling of fluoride in our drinking water. Rather, the EPA recommendation is aimed at setting upper limits to the amount of naturally occurring fluoride in water systems when that amount is in excess of the optimal amount for decay prevention. Thus, under this recommendation, no American will be exposed to more fluoride in the drinking water than exists at present. For the record, there is a direct relationship between the amount of fluoride and the extent of caries reduction, but the relationship is not linear. A doubling of the optimal level of fluoride will result in less than a doubling in the reduction of caries.

Question. With fluoride now present in most major brands of toothpaste, would an increased amount in our drinking water be cause for concern about receiving too much?

Answer. It should be repeated that the EPA is not recommending an increased amount of fluoride in drinking water. Furthermore, it should be noted that no one has demonstrated any health problem at the highest levels of naturally occurring fluoride concentrations in any U.S. water supply. That observation applies today taking into consideration the increased availability and use of fluoride dentifrices, mouth rinses, and other fluoride modalities.

Question. What about the dose/weight rates for small children--can that become a problem?

Answer. Again, it must be stressed that the EPA is not advocating an increase beyond the optimal level of fluoride in drinking, but rather proposing upper limits on naturally occurring fluoride in water supplies. When optimal levels of fluoride were

being established, they were aimed at protecting children's teeth from decay. The provision of any additional fluoride in young children is based on their age, weight, and the amount of fluoride in the drinking water. It is important that children under age 6 use only the proper amount of fluoridated toothpaste and be regularly supervised by their parents. Also, the use of fluoride mouth rinses is not recommended in young children because of the possibility that they may swallow the rinse rather than spit it out. It is worth repeating that no health problem has been found in areas of the U.S. which have the highest naturally occurring levels of fluoride in the water supply.

DENTAL CARIES IN CHILDREN

Question. Based on recent reports, it looks like children in this country have fewer dental caries than before. Is this the direct result of dental research? How will the FY 1987 budget proposal affect such successes in the future?

Answer. There is no doubt that the decline in dental caries in children has been a result of the caries-preventive measures evolving from dental research activities over the past 40 years. The most prominent of these measures have been the multiple fluoride modalities (ranging from water fluoridation to fluoride-containing dentifrices) available to children in community-based programs, in dental offices and at home. Also, the development of dental sealants (plastic coatings applied to the rough surfaces of teeth) has been a critical addition to the caries-prevention armamentarium. Together, the appropriate use of fluorides (which are most effective on the smooth surfaces of teeth) and the use of sealants could virtually eliminate dental caries in children.

Beyond these specific caries-preventive measures there have been several other factors thought to contribute to this decline. These include the healthier eating habits alterations, better oral hygiene, and the use of antibiotics.

The FY 1987 budget proposal may result in a reduction of a variety of caries research activities aimed at improving caries-prevention. These include identifying high-risk groups and developing appropriate prevention measures for them and conducting a follow up study of dental caries in school children to determine if the caries reductions observed in children are being maintained or not.

WORKPLACE HAZARDS

Question. I have been reading that the dental community has begun to wear masks and gloves when treating patients. This is partly due to the fear of contracting AIDS. In your professional opinion, what are the chances of a dentist contracting AIDS by working on a patient who has that disease?

Answer. The AIDS virus has been identified in saliva, but so far no cases of transmission have been documented from casual

contact alone. The best evidence that casual contact does not transmit the disease is in a study of families where one or more family members has AIDS. These family members have not seroconverted within the expected time period for conversion. During dental treatment, saliva is rarely contacted by dental personnel where it is not also contaminated with blood. Therefore, it is prudent to assume that where blood and saliva are mixed, there is a potential for transmission of disease. This applies to other infections as well as to AIDS. Although there have been no studies to date which deal directly with this issue, it should be noted that even in those locales with the highest incidence of AIDS patients no dentist, other than those who are members of the identified risk groups, has been reported to have contracted AIDS.

Question. In March of 1984 Consumer Reports expressed concern over the problem of mercury vapor and other chemical hazards that may be affecting the health of dentists and other employees. Do you think that this is a problem, and if so, have you conducted any studies into this problem?

Answer. Dentists and their employees are exposed to a number of substances including mercury that could have adverse effects on their health if used improperly. Available data, however, indicate that the dental care personnel are aware of this problem and are handling these materials in a manner that keeps the level of exposure within the acceptable range. Recently, environmental scientists have focused their attention on reproductive hazards in the workplace. With the number of women dentists increasing steadily, and the vast majority of dental assistants being women, this is an important area to explore. Consequently, the National Institute for Environmental Health Sciences, with support from the NIDR, is initiating a study on the reproductive effects of exposure to mercury on female dental assistants.

FUTURE PROGRAMS VS REDUCED BUDGETS

Question. What emerging technologies and knowledge provided by dental research do you see directly benefiting society within the next five years? Within the decade?

Answer. The next five years should see some of the fruits of biotechnology coming to the marketplace. These include a new vaccine against oral herpes, new tests to evaluate the cariogenic potential or protective qualities of some foods or food ingredients, and new adhesives and bonding materials for restorative dentistry. Another area of potential importance concerns new ways to manipulate foods and ingredients of foods to enhance their flavor and retard spoilage. As the Institute continues to exploit biotechnology and high technology (in such areas as digitized tomography, laser techniques, nuclear magnetic resonance) it should be possible to diagnose and treat dental and oral diseases earlier.

Some of these new techniques are now being applied to the study of bone-forming cells and to observations of the behavior of

the many factors found in the ground substance of bone or cartilage. Over the decade, these studies may lead to fundamental insights into the causes of the degenerative diseases of bones and joints, such as rheumatoid arthritis, osteoarthritis and osteoporosis, as well as the inherited bone and dental diseases such as osteogenesis imperfecta and dentinogenesis imperfecta. As more is learned about the ecology of the oral cavity and the immune system in the mouth, new ways of preventing the colonization of the oral tissues by pathogens may be forthcoming.

Question. For the record, can you then discuss these new developing technologies in relation to a reduced budget, the amount of delay caused by a less than optimal funding situation and the ultimate cost to society caused by this delay?

Answer. Budget reductions will impede the pace of progress, limiting achievements for any one year. They may also discourage older as well as young investigators from pursuing careers in research, or lead them to abandon the field completely.

AIDS

Question. I have read that scientists supported by the Dental Institute have identified specific immune defects in blood cells that can lead to oral lesions, and that these sores are often the first sign of AIDS. Can you update the Committee on these findings and tell us about their importance to AIDS research.

Answer. Candidiasis is a fungal infection leading to severe and painful oral lesions often seen in AIDS patients. This condition is uncommon in otherwise healthy adults because normal immune defense mechanisms prevent the growth of the causative organism, Candida albicans. Certain white blood cells--monocytes--play a key role in these defense mechanisms because they are among the first cells mobilized to fight infection. These observations led NIDR scientists to study how AIDS affects monocytes.

These investigators have now shown that monocytes exhibit decreased migration towards infectious sites. Not only do the cells fail to accumulate at the site of infection, but they also cannot efficiently kill certain infectious agents, enabling the persistence and dissemination of Candida and other life-threatening infections. The investigators are currently exploring the mechanisms underlying the abnormal monocyte functions and have shown that this cell can be directly infected with HTLV III/LAV, the virus responsible for AIDS. Their current studies are focusing on the mechanisms whereby the virus infects the monocytes with the intention of finding chemotherapeutic and immunomodulatory agents to prevent or reduce infection and depressed function of this cell.

AIDS: REPROGRAMMING PROBLEMS

Question. How much money will your institute receive specifically earmarked for AIDS research in FY 1986?

Answer. In FY 1986, the NIDR will receive $1,712,000 earmarked for AIDS research.

Question. How much money will you spend on AIDS research in FY 1986?

Answer. The Institute will spend all earmarked funds $1,712,000 in FY 1986 on AIDS research.

Question. How much of this money had to be taken or reprogrammed from other activities, functions or programs?

Answer. Reprogramming will not be required to support the Institute's research on AIDS.

Question. For the record, please list all activities, functions of programs that were raided for this purpose and describe the specific impact on each.

Answer. As stated above, no reprogramming will be required to support the Institute's research on AIDS.

Question. Please provide the Committee the same information for personnel changes caused by an FTE shortage in the areas of AIDS-related research.

Answer. The NIDR was provided an additional 4 FTE's for AIDS research by the Director of the NIH.

PAIN RESEARCH

Question. I understand that considerable advances have been made in the development of safe pain-killing drugs that really work. Please bring the Committee up to date on this research. How much of this work has already been brought to the chairside?

Answer. Research recently completed at the NIDR Pain Research Unit has shown that new anti-inflammatory analgesics (flurbiprofen) combined with new long-lasting anesthetics (etitiocaine) can help suppress acute post-surgical pain, such as pain experienced following third molar extractions. NIDR has informed practicing dentists of the clinical benefits of these drug combinations through research publications and professional meetings; many dentists are starting to use these new drugs to give their patients better pain relief with fewer side effects. Later this spring the NIDR is co-sponsoring with the National Cancer Institute, the National Institute of Neurological and Communicative Disorders and Stroke and the Office of Medical Applications of Research of the N.I.H. a Consensus Development Conference on an integrated approach to the management of pain.

Results of this meeting will be widely distributed to dental and medical professionals.

NIDR-supported grantees are also examining the effects of drug combinations used to control chronic pain conditions such as temporomandibular disorders. Results indicate that patients suffering from these disabling conditions often show improvements when treated with tricyclic antidepressants. Furthermore, ongoing research indicates that the tricyclics work at serotonergic and noradrenergic synapses implicated in the endorphinergic analgesia system (that is, the body's own natural pain-controlling system). Thus, the improvements seen are not attributable solely to changes in the patient's psychological mood.

Question. Are we spending enough in this area?

Answer. At the level of the 1987 budget we will address public and professional concerns regarding the safety and efficacy of some drugs or drug combinations used in dentistry through a commitment of contract funds. These will be used for multi-center controlled clinical trials to verify the safety and efficacy of drugs used for dental anesthesia. In addition, interagency agreements are planned to evaluate the safety of prenatal exposure to lidocaine and chronic prenatal exposure to nitrous oxide, in association with the National Institute for Environmental Health Sciences and the Food and Drug Administration's National Center for Toxicological Research.

DENTISTRY AND THE ELDERLY

Question. People are living longer, healthier lives and the National Institute on Aging projects that by the year 2030, people over the age of 65 will make up 20% of our population. The 85-plus age group is growing at almost three times this rate. What research are you supporting that concerns the dental problems of the elderly? In your professional judgment, are we allocating enough of our resources to this area?

Answer. The NIDR had stated in Challenges for the Eighties, the Institute's Long-Range Research Plan FY 1985-89, that increasing attention would be paid to delineate the oral health problems in these age groups with the aim of finding improved treatments and prevention.

A major step was taken in 1985 and in 1986 with an epidemiologic survey to measure the oral health status of working adults and the elderly. Oral examinations were conducted on 20,000 adults at workplaces and at senior citizen centers and by the end of 1986 preliminary data will be available to specify the extent and severity of dental caries, of periodontal diseases, of tooth loss and other oral conditions in these groups. This information will be used to direct research efforts where they are most needed and especially to expand oral health promotion and disease prevention interventions tailored to adults.

A second major effort has been the research emphasis on the periodontal diseases and on root caries. The causes and consequences of the periodontal diseases are being further

elucidated. Fortunately, new and effective means of preventing the development of periodontal disease should soon be available in the form of antimicrobial mouthrinses that dentists will be able to prescribe. The problems of root caries, a form of decay found when the tooth roots are exposed due tc gingival recession, are now being addressed at several of the NIDR-supported Dental Caries Research Centers.

A third important initiative concerns a collaborative project on oral health needs of the elderly involving the NIDR, the National Institute on Aging, and the Veterans Administration. This effort has resulted in the development of a research agenda that makes recommendations in major areas, ranging from studies of normal age-related changes in oral tissues to research on ways to adapt dental service delivery to the needs of older people, whether they are healthy and active or frail and institutionalized. This document, called A Research Agenda on Oral Health in the Elderly, is now in press at the Veterans Administration. All three agencies will publicize the availability of the Agenda and will distribute it at major professional meetings. Copies will also be supplied to members of this Committee. Interested individuals may also request a second document, A Catalog of Resources, which briefly summarizes the kinds of research and resources available at each of the three Federal agencies. With these documents as a basis, the NIA, the VA, and the NIDR will develop an implementation plan. This plan will select specific areas of research recommended in the agenda that lend themselves to interagency collaboration, in this way making the best use of the unique talents and resources of each agency.

COST OF DENTAL CARE

Question. What is the National dental bill, and how much has been saved by the practice of modern dentistry?

Answer. According to the Department of Commerce, the Nation's dental expenditures for personal dental services were $19.8 billion in 1984. The 1985 figure is not final, but it is estimated to be $21.0 billion.

The growth in expenditures has slowed dramatically since 1970 for a number of reasons, including community water fluoridation, better oral hygiene habits, and preventive services provided by practicing dental personnel. If expenditures had not slowed, the Nation's dental bill for last year alone would be almost $5.0 billion more--even after adjustment for inflation.

TRAINING

Question. I know that one of the priorities of your Institute's program is to increase the number of competent dental researchers. What progress has been made in this area?

Answer. We have made a very good beginning in this priority initiative. The Dentist Scientist Award (DSA), which was especially designed to prepare dentists for careers in dental research was implemented in June 1984. In addition, the NIDR provides support for those dental applicants who have already completed advanced clinical training under the parallel Physician Scientist Award (PSA).

Question. What will be the effect of the President's budget proposal on this priority?

Answer. The NIDR FY 1987 budget will allow for the continuation of support for all candidates already participating in the Dentist Scientist and Physician Scientist Award programs, but will not allow for the admission of the next group of scholars to the 5-year program.

Question. If this reduction continues, what, in your professional judgment, will be the impact on the future dental health of our citizens?

Answer. The ability to advance dental research and, most importantly, effect the transfer of basic knowledge into clinical practice is dependent upon the availability of a cadre of highly qualified dentist scientists. Progress in meeting these objectives will be slowed.

CENTERS

Question. This past year, the NIDR submitted a report to Congress on your Institute's plans for research centers. Please give us an update on the progress you have made in implementing these plans.

Answer. Following the October 1985 transmission of the report to Congress, the NIDR issued a program announcement to inform the dental research community of our planned future use of centers and other large grants. A specific request for applications (RFA) was issued in December 1985 for Research Centers in Oral Biology (RCOB). This RFA reaffirms the Institute's commitment to support multidisciplinary research centers that focus on basic science and related applied problems relevant to oral health and disease. The RCOB program, which provides for open competition, will replace the current Dental Research Institutes and Centers (DRIC) program which has been supported by the NIDR.

Question. How will the FY 1987 budget proposal affect these plans?

Answer. The FY 1987 Budget provides for 16 centers, the same number of centers as in FY 1986, with a reduction of $1.517 million in available support. The NIDR will, therefore, limit competition to the number of centers coming up for renewal. In addition, the initiation of the new core grant (P30) program

recommended in the report to Congress will be deferred as will the further development of the ongoing categorical/thematic research center grant program.

PREVENTION

Question. We are aware of the efforts you are conducting and supporting to prevent periodontal disease. Please provide a status report on new chemotherapeutic approaches to the control of plaque and gingivitis. When will the American public begin to benefit from this preventive approach?

Answer. Several chemotherapeutic approaches are being followed in our research programs and they are at different stages of development. One agent known as chlorhexidine which controls the development of supragingival plaque and gingivitis has been used widely in Europe as a mouth rinse. Approval by Federal regulatory agencies is currently being sought for use of the agent in this country. The NIDR is currently conducting a clinical trial to test the efficacy of a stannous fluoride mouthrinse to reduce plaque and prevent gingivitis. A preparation of this type may be marketable within 2-3 years. In addition, we are supporting research at nonprofit institutions and at small business enterprises to develop controlled release antibacterial agents which will not only control supragingival plaque associated with gingivitis, but will also prevent bacterial growth deep in periodontal pockets for longer periods, perhaps for weeks and months. Such agents with appropriately controlled release delivery systems may be available on the market within 3-5 years.

GRAMM-RUDMAN-HOLLINGS EFFECTS

Question. If the automatic provisions of Gramm-Rudman-Hollings are triggered in FY 1987, your Institute may well have its budget reduced by 20-25%. Have you prepared a contingency plan in the event Gramm-Rudman-Hollings becomes reality? If so, please send a copy of your plans to this Committee. If cuts of this magnitude become reality, how will they be distributed:

1. Intramural vs extramural programs;
2. Peer review system:
   Would number of site visits be reduced?
   Would travel to NIH to study section meetings be affected?
3. Would NIH employees have to be furloughed?
4. What major programs would have to be cut back?

Please list the research programs of the highest priority that should not be cut and why.

Answer. The FY 1987 budget for the NIDR was developed in compliance with the Gramm-Rudman-Hollings Act. We saw no need for any further sequestration of funds and so we have not developed a specific contingency plan. Further budget reductions would affect

all programs and require careful review to decide which programs, if any, might have to be eliminated. Substantial cuts would also have to be made in administrative expenses.

PRIVATE SECTOR COLLABORATION

Question. Assuming we will face limited budgets for a while, what is the NIDR doing to investigate the potential for collaboration with private industry to carry out needed dental research?

Answer. The NIDR has a long history of collaboration with private industry in many areas of research. To further this joint effort, the NIDR will hold a one-day meeting this Spring, inviting some 60 firms with interests in the dental field. The agenda includes presentations by intramural program scientists of research that is of potential commercial interest. Representatives of industry will also be invited to speak from their perspective about matters of mutual interest. We hope that this meeting will stimulate increased collaborations between the NIDR and industry.

PRIVATE SUPPORT FOR ALL DENTAL RESEARCH

Question. Do you think it is possible to finance all dental research through private sources?

Answer. No. Most scholars agree that private commercial interests could not and would not support the basic open-ended research conducted by scientists with disinterested curiosity to understand how the world or how the human body works. Moreover, philanthropic foundations, health voluntary agencies and other non-profit sources of research funding in the United States are not focused on dental research in particular and do not command the resources needed. Moreover, the very fact that there exists a single component within the National Institutes of Health that is the central focus for oral health research in the country has helped the research effort. There is both visibility and a track record of notable achievements that have spurred the research effort and accelerated the advancement of dental research since World War II.

IDENTIFYING INDIVIDUALS AT RISK

Question. Do you have any efforts underway to identify individuals who are most at risk for either dental caries or periodontal disease?

Answer. There are several studies under way which should improve our ability to determine which individuals are most at risk for either dental caries or periodontal diseases. These studies are investigating the microorganisms associated with these diseases, the genetic basis of localized juvenile periodontitis, and exploring a variety of variables such as dietary intake and clinical indicators that are being incorporated into predictive

models. In June 1986 the NIDR is sponsoring a state-of-the-art conference to assess current methods for the identification and quantification of microorganisms associated with these diseases.

ANTI-HERPES VACCINE

Question. Last year you reported success with an experimental anti-herpes vaccine. Could you give us an update?

Answer. Last year we reported on a genetically engineered vaccine for herpes simplex type 1 (HSV-1) which was a vaccinia virus recombinant expressing the gene for glycoprotein D of HSV-1. The vaccine protected mice against lethal challenge with both HSV-1 and HSV-2 and showed considerable protection against the development of a latent infection with HSV-1. We have verified that mice immunized last year are still protected against infection and are continuing to conduct tests of the duration of the vaccine and the effects of booster shots. Trials in human subjects are anticipated, pending the completion of animal studies and the resolution of safety issues regarding the reintroduction of vaccinia virus as a vector.

Also, an NIDR grantee has developed a synthetic form of a small portion of the glycoprotein D which may be an effective immunogen in itself, not requiring the use of vaccinia virus as a vehicle.

BIOTECHNOLOGY

Question. You have emphasized how far dental research has come in joining mainstream biomedical research, especially in areas of biotechnology. Would you provide specific examples of progress in this area?

Answer. Here are several examples:

Recombinant DNA methodology is being used to study potential periodontal pathogens such as Actinomyces viscosus and their establishment in the oral cavity. The genes coding for cell surface components responsible for the attachment of these organisms to other bacteria or to oral tissues have been cloned and these proteins are being studied to find ways to prevent attachment and resulting disease.

A recombinant herpes simplex virus (HSV) vaccine combines vaccinia virus with the gene for glycoprotein D of HSV-1. The vaccine in tests in the mouse is efficient against lethal and latent HSV-1 and HSV-2 (genital HSV) infections.

Basement membrane studies. Recently cloned genes for the B chain of laminin have been cloned. Laminin is a structural glycoprotein unique to basement membranes. It has an effect on growth and development of a variety of cells. It also is a focus of interest in cancer research since metastatic cells have a strong affinity for laminin and specific collagenase to dissolve the membrane and invade tissues.

Bone matrix. NIDR scientists have cloned the genes for osteonectin and bone proteoglycan, two important constituents of bone matrix and bone formation. Alterations in cartilage proteoglycans are being studied for clues to osteoarthritis pathology.

Monoclonal antibodies have been made against osteonectin. A radioimmune assay has been developed and is being used to measure serum levels of osteonectin to aid in diagnosis of bone diseases and as an indicator of efficacy of treatment.

A new method for isolation of cells producing monoclonal antibodies has been developed. This method is being used to study antibodies against normal cellular constituents as found in autoimmune diseases.

Questions Submitted by Senator Arlen Specter

COLLABORATIVE EFFORT ON ORAL HEALTH IN AGING

Question. In your statement on the priorities of the National Institute of Dental Research, Dr. Löe, you mention a joint effort with NIA and the Veterans Administration. Would you elaborate on this venture and the VA's role in it?

Answer. Recently all three agencies had developed plans emphasizing the need to expand research in all areas of health of the elderly. It seemed an excellent approach to combine efforts in a focus on oral health in the elderly, until recently, a largely neglected area. The VA conducts research and supplies dental and medical care to some 3 million veterans, a group that is already older-aged and often with complex and severe physical and sometimes mental problems. By combining resources, patient populations, particular training environments and programs, the 3 agencies saw the potential for fruitful research and research training opportunites, thereby capitalizing on each other's unique capabilities at a time when all agencies face budgetary constraints.

ADEQUATE SUPPLIES OF FLUORIDE

Question. Also, Dr. Löe, according to information available to me some localities have been having difficulty obtaining adequate supplies of fluoride with which to treat their water supplies. What short and long range health effects would you foresee if this continues and what research does NIDR plan to monitor these effects?

Answer. Losses of protection against dental caries would definitely result from long-term discontinuation of fluoridation in places where it has been in effect more than a few years. Specific studies of the dental health losses associated with the discontinuation of sub-optimal maintenance of water supply fluoridation have been carried out earlier in the U.S., Scotland, and the German Democratic Republic. In a major city in the German Democratic Republic, for example, fluoridation was begun in 1959

and continued through 1971. The city then suffered a 3-year period of erratically lower fluoride concentrations that at times were less than 10 percent of the optimum. By 1975, about 4 years after the control problems began, the 10-year-olds had a caries rate close to double the rate they had experienced with optimum fluoridation. After 1978, with optimum fluoridation re-established, the rates were decreasing. These observations confirm earlier similar findings in Antigo, Wisconsin; Austin, Minnesota; and Kilmarnock, Scotland.

Fortunately, up to now, the shortages of fluoride chemicals in U.S. communities have not persisted long enough to produce measureable negative effects, although any lapse of fluoridation should be viewed as disadvantageous to dental health. National baseline data are being maintained so that we will be able to measure any change resulting from discontinuation of water fluoridation.

Questions Submitted by Senator William Proxmire

FUNDING FOR COLLABORATIVE RESEARCH ON AGING

Question. Dr. Löe, on page 7 of your prepared statement you refer to a Research Agenda on Oral Health in the Elderly that will form the basis for joint research projects with the National Institute on Aging and the Veterans Administration. Can you tell us how much each agency will contribute to this joint research endeavor in FY 1987?

Answer. The three agencies involved are in the process of developing an Implementation Plan, selecting projects listed in Research Agenda that lend themselves to two- or three-way collaborations. All three agencies are giving visibility to research needs in this area to stimulate grant applications and research training in the field. This could lead to program announcements, requests for applications, workshops, or other means of alerting the research community.

AIDS RESEARCH

Question. Dr. Löe, about 15 percent of your prepared statement is devoted to a description of the work on AIDS being done through your Institute. However I note that your AIDS budget for the current fiscal year is only $684,000 and that you are requesting the relatively modest sum of $2,768,000 for AIDS research next year. Can you tell the Committee how you have have been able to accomplish so much on quite limited resources?

Answer. The NIDR FY 1986 support for AIDS research is estimated to be $1,712,000. Several of the projects involving research on AIDS are natural extensions of work that was already being conducted in the intramural research laboratories. Other research investigations are in their preliminary stages or just being initiated.

DENTAL RESEARCH AND DIABETES

Question. On page 235 of your justification you discuss work on juvenile diabetes. Although your exploration of bioinfections as a possible cause of diabetes sounds exciting and most rewarding, I am curious as to how the chief Federal agency supporting research on oral health and disease became involved in this area. Can you tell us how this came about?

Answer. Diabetes is a disease which has profound oral involvement resulting in increased oral infections, periodontal disease and dry mouth. NIDR intramural scientists have, over the years, conducted outstanding research on virology and immunology, on collagen and on the biochemistry of basement membranes. Dental scientists established that beta cells in the pancreas could be infected by viruses, leading to an infectious model of diabetes in animals. The National Commission on Diabetes, established by Public Law 93-354, July 23, 1974, was charged with formulating a long-range plan to combat diabetes. In this plan, delivered to Congress on December 10, 1975, the Commission listed the National Institute of Dental Research as one of the Institutes of the NIH with responsibility to implement diabetes activities at the NIH.

GRADE CREEP

Question. Dr. Löe, there seems to be a certain amount of grade creep at your Institute. Last year you estimated you would carry 16 GS/GM-14's in 1985 and 1986. This year's justifications show 18 GS/GM 14's and a projected 19 such positions this year/ Can your budget officer give us the reason for this grade creep?

Answer. The figures represented in the chart in the Justification to which you refer are a projection of the promotions and recruitments which the Institute anticipated would be occurring during the fiscal year. The FY 1986 GS/GM-14 level remained at 18, while the GS/GM-15 level projected to be 18 will actually become 15--3 fewer than originally anticipated. Thus the end result is a grade de-escalation rather than a grade creep.

BUDGET SHIFT

Question. Last year in justifying a 1986 budget request of $93,439,000 you indicated in your justification that $18,336,000 would be devoted to disorders of structure, function and behavior. A look at your current 1986 plans indicates that you will spend only $15,442,000 in this area although your total budget is about $4.6 million more than initially requested. Can you tell us why you decided to shift these resources to other areas?

Answer. Last year, the program activity entitled "Disorders of Structure, Function and Behavior" consisted of 4 programs: Restorative Materials; Soft Tissue Diseases; Craniofacial Anomalies; and Pain Control and Behavioral Research. In order to represent this program activity more accurately, the Restorative Materials and Soft Tissue Diseases

programs were removed and relocated under "Diseases of the Teeth and Supporting Tissues." This transfer of funding for Restorative Materials and Soft Tissue Diseases from one program activity to another results in the appearance of a reduction in funds. However, there has been no actual reduction in funds for this important activity.

SUBCOMMITTEE RECESS

Senator WEICKER. The subcommittee will stand in recess until next Monday, March 10, and we will meet at 9:30 a.m., in this room. At that time we will again hear from the National Institutes of Health with testimony from the following Institutes: the National Heart, Lung, and Blood Institute; the National Institute of Arthritis and Musculoskeletal and Skin Diseases; the National Institute of Diabetes, Digestive and Kidney Diseases; the National Institute of General Medical Sciences; and the National Institute of Child Health and Human Development.

Thank you all.

[Whereupon, at 11:05 a.m., Thursday, March 6, the subcommittee was recessed, to reconvene at 9:30 a.m., Monday, March 10.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1987

TUESDAY, MARCH 11, 1986

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:53 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker and Proxmire.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

STATEMENT OF DR. MURRAY GOLDSTEIN, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

WILLIAM MATTHEWS, BUDGET OFFICER, NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

TRIBUTE TO SENATOR JACOB JAVITS

Senator WEICKER. I apologize for my tardiness, but just to make you all feel better, since 5:30 this morning, I have been in airports or airplanes, so it is not a question of tennis matches, or sitting on the sand in Florida.

I would also like to say that yesterday, the reason why we postponed our hearings was because of the funeral of Senator Javits, which was a very moving experience.

I think that it is entirely appropriate that I mention at this particular point in the hearings the work that Senator Javits accomplished after he left the Senate, especially as it related to the National Institutes of Health. Truly, if ever there was proof of the power of an idea and of a man, rather than a position, it is the fact that Jack accomplished all of that without the title of Senator.

I think that this pretty much stands as testimony to the fact that that man has shaped many lives in this country by virtue of his integrity, and by virtue of his compassion. He really never needed the official title, he did it by virtue of his eloquence, his mind, and his energy.

I know we are going to hear more of this throughout the preparation of the budget, but I would say that, like so many other areas of his endeavor, his epitaph is really not written in stone, but rather in all of our lives.

In any event, before this hearing is over, I am going to go ahead and reschedule the hearings which were postponed yesterday because of the funeral. I will try to go ahead and somehow work it in this week. I don't like to get off of the train of thought once we are on it. Before the end of this hearing, I will have my calendar down here, and we will try to work this out either tomorrow, Thursday, or Friday, or something of that nature.

I understand that there are several persons from the institutes who won't be around next week, who have other plans, and I want to make sure that we keep this together as a whole, to the extent possible.

Our first witness this morning is Dr. Goldstein, the Director of the National Institute of Neurological and Communicative Disorders and Stroke. It is nice to see you again, doctor.

Dr. GOLDSTEIN. Thank you, Mr. Chairman.

May I introduce Mr. William Matthews, the chief of our Institute's financial management office.

SENATOR JACOB JAVITS

I would like to use this opportunity, sir, to report that Senator Javits visited NINCDS about 1 year ago and spoke to our staff. It was a very thrilling experience because here was an audience of people who are dedicated to biomedical research, and after the Senator's presentation, there was a hush in the room. He really touched the audience about the impact of what they were doing.

I am very proud to say that among the living memorials to the Senator, we now have 150 Senator Javits investigator awards active at the moment, as well as four Senator Javits research centers. What greater tribute can we make to a person's accomplishments than that kind of activity; it is certainly more impressive than a statue.

Senator WEICKER. Thank you.

Dr. GOLDSTEIN. I have submitted my statement for your appraisal and review, sir, but I would like to touch on three research issues which I think the committee would find of particular interest.

EXTRACRANIAL/INTRACRANIAL ANASTAMOSIS

The first is that a number of years ago, a surgical procedure was developed that was extraordinarily logical; namely, it could bring blood to that part of the brain which was deprived of it because of an occlusion of a brain blood vessel. A very simple surgical procedure was developed that carried the name extracranial, outside the skull, intracranial, in that

a blood vessel from the scalp was plugged in beyond the vessel occlusion, and provided for recirculation of the brain in a patient having a stroke.

This was a simple procedure, and one that had logic in support of it. It has become one of the most popular neurosurgical procedures in the United States, requiring about $30 million a year in health care costs.

We have just completed a 9-year controlled clinical trial, the results of which have been published. I am sorry to say that the procedure is worthless for the prevention or treatment of ischemic stroke. The bad news is that the procedure is worthless, but the good news is that approximately 30 million dollars' worth of annual health care costs will no longer be imposed upon our economy. The operation doesn't work.

Of equal importance, since there was a little over 2 percent mortality rate associated with the surgery, people will now be protected from that mortality. So a carefully planned clinical trial, involving 1,400 patients, has now been completed at a cost of $9 million. The study results will clearly save both our population from morbidity and mortality, and $30 million a year in health care costs.

RESTITUTION OF FUNCTION

The other issue I would like to bring to your attention is one of the most exciting of all areas of neuroscience research at the moment. It is still a basic science area, and it is called restitution of function.

We are all born with about 10 billion brain cells. We were taught, at least in my upbringing, that a brain cell was so highly specialized that it had lost its ability to repair itself. Once it was damaged, that was often its end. Fifteen years ago, I could have sat before this committee and made that statement as if it was the 11th commandment.

I am delighted to say that I was very wrong. That is not true at all. The hard fact of the matter is that we are now on the brink of retaining its viability and restoring function to that damaged nerve cell. We are now able to take a brain cell and help it to grow so that its process can go from the brain down to the tailbone. That nerve cell process can regrow the entire length of the spinal cord in an animal model of spinal injury.

Within 2 to 3 years this will be a standardized experimental procedure. The problem we now face is influencing that growing process so it will know where to go. Quite obviously, if the process was supposed to go from the brain to the big toe and instead went to the bladder, we would be in trouble.

So the question is, what controls where the site of connection is to be? We have evidence that we are beginning to understand the answer to that question. It is premature for me to discuss our hypothesis at this time. It is still quite experimental. But the hard fact of the matter is, we are getting on with it. Perhaps in our lifetime we will have the biological information that will permit people to have function restored that has been lost due to spinal injury, due to stroke, due to MS, and maybe ALS, but that latter is more problematic.

BRAIN CELL IMPLANTS

Within this area of restitution of function, we have one other exciting development. As I said previously, we are born with about 10 billion brain cells, and we are not going to have any more. Well, perhaps we may have more because there is now a procedure being actively investigated in animal models in which brain cells are being placed in the brain, in an area of brain cell destruction.

We know that the new brain cells can survive there. We know that other parts of the brain can innervate them, so that their activity can be controlled. We know that they do not become neoplastic.

We know, that at least as far as neurotransmitters, they can produce the neurotransmitters that are needed and that have become deficient. The most obvious example of this is in the Parkinson's disease syndrome. In a chimpanzee model, we can restore function to the chimpanzee that has become Parkinson-like because of a chemical that destroys a specific part of the brain.

We have not used this procedure of brain cell implants in humans in this country, and we must be very careful before we do. We still have important experimental information to obtain. Again, the point is that for the first time we have evidence that we can enter the human brain and restore function that has either been damaged or completely destroyed by placing brain cells in the damaged area.

We use the term brain implant. I try to avoid the term brain transplant, because that has connotations about replacing the whole brain. We are talking about cells, and not replacing a large area of the brain.

So restitution of function after nervous system destruction is a potential reality. It is a biological probability. I would expect that in future hearings, hopefully in the reasonably near future, I can talk about success.

AIDS DEMENTIA

The final issue that I would like to call to your attention is a follow-up of the discussion this subcommittee had several days ago about AIDS.

We have come across a rather surprising, perhaps alarming issue. We now know that a number of patients who have complete dementia, sometimes with no other symptoms of AIDS, are admitted to hospitals and are found to be sero-positive to the AIDS tests. Then, on death, autopsy demonstrates that the brain has been invaded by the AIDS virus.

The problem with this is, as we know, the brain is often immunologically privileged. The question that we are concerned with is, can the AIDS virus take up housekeeping in the brain and exist there without an immune system response? If that is true, can it then reproduce itself, and release additional AIDS viruses over time?

What is even more of a problem is that we now know of four patients who have died with what we call AIDS dementia, who were serum negative, had no immunological response at all, yet had neuro-

logical AIDS. On death, autopsies clearly demonstrated their brains to be infected with the AIDS virus.

This is a new area of AIDS infection of which we were not aware. Research is being coordinated with Dr. Anthony Fauci and his committee, the NIH AIDS Executive Committee. The NINCDS is actively moving ahead in this research area.

If the brain, in fact, is an environment in which the AIDS virus can live without affecting the rest of the body, without giving out signals, we obviously have a brain time bomb on our hands. We will keep the committee informed as we develop more information.

Sir, those are three research areas that I would like to call to your attention. I hope my statement clearly describes the others. With that, sir, our budget request for fiscal year 1987 is $399,351,000.

PREPARED STATEMENT

Senator WEICKER. Thank you. We will insert your full statement in the record at this point in its entirety.

[The statement follows:]

Statement of Dr. Murray Goldstein

During the past thirty years, the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) has focused its attention on the support and conduct of intensive research on the basic neurosciences and communicative sciences to serve as the basis for clinical advances. As a result and with the development of a broad core of understanding about the organization and pathology of the brain and nervous system, we are now prepared to reap the benefits of this focused activity; we are organizing the required research teams to intervene in some of the more than 650 neurological and communicative disorders that devastate the lives of millions of Americans and their families. These varied diseases affect all parts of the brain, the central and peripheral nervous systems, muscles and soft tissue, as well as being a central factor in dysfunction of the immune and endocrine systems. Some of the diseases under our purview, such as stroke, kill their victims, adults or children, outright while others such as Batten's, Huntington's, Tay Sach's and Alzheimer's disease result in a lingering slow life-in-death with victims robbed of their mental and physical powers. Still others, such as amyotrophic lateral sclerosis (ALS), destroy the body's mobility, leave the brain intact, but eventually kill its victims. As Senator Jacob Javits put it so vividly: "The living dead." Autism, hearing problems, aphasia, attention disabilities and epilepsy wreak havoc on the mind and our ability to function in society. Many neurological disorders are inherited or have a genetic component. Neurofibromatosis, tuberous sclerosis, Joseph's disease, Huntington's disease, Gaucher's disease and the other lipid storage diseases are passed on from parents to children. Some neurological disorders are even more mysterious. Tourette syndrome, with its uncontrollable outbursts, currently intractable forms of epilepsy, severe Parkinson's disease, myasthenia gravis, multiple sclerosis with all of its variations destroy the patient's life and add unmeasurable stress to families. Not only is the disability associated with these diseases destructive, but also the unpredictability of an attack or exacerbation further confounds the very act of living. We must remember that the impact of these diseases do not generally diminish over time. They are chronic; patients get worse. To date we have had few effective and safe therapies. The maladies are mysterious, complicated, and so far most have been resistant to the concerted efforts of our best minds.

But this is now changing. We are learning how to help and in some diseases to discard commonly used therapies which are of no value. In a few cases we can stem the tide of the illness. In other cases, we can control the symptoms and slow the still inexorable path of the disease. Further, research is clarifying current medical and surgical practices. For example, this year in a major international clinical trial, scientists supported by NINCDS discovered that a widely used neurosurgical procedure to direct blood past obstructed brain arteries is no more effective--and much less safe--than available medical therapy for preventing stroke. We now know that this commonly done surgical procedure, the extracranial/intracranial (EC/IC) bypass operation, should be abandoned as a therapy for stroke. The potential savings are immense, as an EC/IC operation costs an average of $15,000 and

several thousand are performed in the United States each year. We are now preparing to evaluate the effectiveness of one of the most commonly performed surgical procedures in the U.S., carotid endarterectomy for the prevention of stroke. In addition, new pharmacologic methods are being developed and evaluated for protecting the threatened brain cell during the acute stroke period.

New epilepsy treatments are also emerging. Just as we discover serious and unwanted side effects with barbiturates, long an important part of antiepilepsy drug therapy, new surgical techniques are beginning to help those epilepsy patients whose seizures have not been controlled by drugs. Scientists are exploring such new experimental diagnostic techniques as magnetoencephalography (MEG), a sophisticated recording of the magnetic fields generated by the brain, to pinpoint the exact brain abnormality. With modern imaging techniques physicians are able to perform microsurgery and excise even the tiniest lesion responsible for the abnormal discharges of epilepsy.

Biotechnology advances are starting to make inroads in primary brain tumors, such as the gliablastomas, long recognized as among the deadliest of cancers. Little progress has been made in treating many primary brain tumors by conventional pharmacologic, radiation or surgical means; most of these tumors are difficult to treat and the prognosis is often poor. We are applying the technology of monoclonal antibodies and other emerging tools of the biotechnology revolution to improve the targeting of chemotherapy to the tumor. We are very excited right now by an NINCDS intramural project using fresh tumor cells treated with Interleuken-II to attack deadly glial brain tumors. These cells, produced from the live tumor cells of the individual patient, theoretically can attack each part of the highly diversified tumors and, thus, may be better able to destroy the tumor. The preliminary results are very promising. At therapeutic doses the treatment appears to be safe and nontoxic to the patient, a rarity in cancer treatments. Neuroscientists' efforts to understand and control Acquired Immune Deficiency Syndrome (AIDS) have also increased in the past year. To cite one example, scientists have discovered that AIDS is sequestered and replicates in the cells of the brain, perhaps even when it is quiescent in other parts of the body. Because the blood-brain barrier prevents most drugs from entering the brain, AIDS researchers now must not only find effective therapies for this deadly disease, but in cooperation with brain scientists must also devise a way to deliver it to the site of infection, the too-well protected brain.

The brain and the central nervous system are simultaneously sturdy and vulnerable. Once injured, once function is lost, restitution of function is difficult and could be impossible. Serious spinal cord injury and resulting paralyses have long been viewed as permanent. While at the moment we must still accept such injuries as immutable, we are beginning to develop the information necessary to challenge these theories. First, we are working to prevent the initial insult in a host of conditions including stroke, Parkinson's disease, and hearing disorders, as well as in spinal cord and head injury. Second, we are learning how to reverse these injuries and their effects and to restore function to a damaged nervous system; however, we cannot do it yet. The knowledge base is growing which may someday make available effective treatment

of those diseases that now destroy parts of the brain and the central nervous system.

For example, in a recently completed controlled pilot study of Copolymer I in exacerbating-remitting multiple sclerosis, a frequent form of the disease, there was a significant reduction in the frequency of MS relapses in the Copolymer I group over the control group in the two years of the study. At the end of the trial, the patients treated with Copolymer I are significantly less disabled than their counterparts in the control group. Each MS attack causes additional scarring and loss of function of the central nervous system; the patient recovers less completely from each exacerbation. If we can decrease the number of attacks, we may halt the relentless loss of function associated with MS. We hope to learn more in a full-scale clinical trial of Copolymer I.

Another way to restore lost function is with a neural-prosthesis. The first but relatively crude cochlear implants are already available to help the profoundly deaf, but the future holds much more promise. While existing implants allow the wearer to identify the existance of sound and some of its coarse characteristics, multi-channel models now being designed may permit the profoundly deaf patient to discriminate between a telephone ring and a doorbell chime. Eventually, using computer assisted speech processors, the deaf should be able to interpret the electrical impulses of the human voice as actual, intelligible speech.

In past decades stroke treatment has seen little change; physicians have been powerless to stop the brain damage once the stroke begins. The findings of basic research are changing that unsatisfactory situation. For example, stroke patients used to be given intravenous solution containing glucose as soon as they were admitted to the hospital. Now we realize that glucose "over-feeds" the brain and actually acts to further threaten damaged brain cells. Stroke is now being treated with an entire armamentarium of modern medicine to keep brain cells alive until the acute stage of the stroke is arrested and the brain can make use of its amazing powers of survival. Scientists have discovered that brain cells deprived of oxygen and necessary fluids do not die immediately but can be maintained and regain function many hours after the initial injury. These exciting findings are preliminary, but point the way to further stroke and trauma research and demonstrate the ties and strong relationship between basic and clinical research.

Head and spinal cord injury destroy the lives of thousands of young Americans each year. Currently, only supportive and rehabilitative care is available; as yet effective methods are not available to treat paralysis or the seriously damaged spinal cord. In the past few years things have begun to change. Scientists using modern plastics and the techniques of bioengineering are learning how to allow a damaged nerve cell to grow again and even to grow within appropriate neuron bridges to their appropriate targets. While this work is still in its infancy, it is very promising and offers hope that indeed some day the paralyzed may walk again.

The implications are enormous. We anticipate these early results of basic science as they are eventually applied to the damaged nervous system will improve the quality of life of trauma patients as well as for patients with Alzheimer's disease, Parkinson's disease, or ALS. Thus, in addition to prevention as a primary goal of NINCDS research, restitution of function has also been designated as a primary target.

The ties between basic and clinical sciences, between science and medicine grow stronger and are our major modus operandi. Our commitment to basic research remains unwavering. An example of this commitment is our Javits program, mandated by the Congress. The NINCDS now supports 147 Javits scholars, each of whom is investigating a key, yet unsolved issue, in the neurosciences or communicative sciences. Demonstrating the importance of multi-disciplinary, comprehensive research centers are the four NINCDS Javits Centers of Neurosciences Excellence.

The NINCDS research program has reached its second milestone. The first was developing and establishing a cadre of basic and clinical scientists superbly trained in the "new" biology. The second milestone was the reevaluation of the understanding of the brain, the nervous system and human communication and recognizing its unique molecular and neurochemical properties. With a new core of understanding about the neurological and communicative system, the NINCDS is prepared to address the third issue of Institute responsibility--the prevention of neurological and communicative disease and the restitution of function where damage has been done by disease, trauma or genetic dysfunction.

Our budget request for FY 1987 is $399,351,000. I am pleased to answer any questions you might have.

Biography of Dr. Murray Goldstein

October 13, 1925, New York, New York

EDUCATION: B.A., New York University, 1947; D.O., Des Moines Still College of Osteopathic Medicine, 1950; M.P.H., University of California, School of Public Health, 1959.

PROFESSIONAL HISTORY: Director, NINCDS, 1982-present; Acting Director, NINCDS, 1981-1982; Deputy Director, NINCDS, 1978-1981; Medical Officer, Commissioned Corps, PHS (Assistant Surgeon General), 1953-present; Director, Stroke and Trauma Program, NINCDS, 1976-1978; Director, Extramural Programs, NINCDS, 1961-1976; Visiting Scientist, Mayo Clinic and Graduate School, Rochester, Minnesota, 1967-1968; Chief, Special Projects Branch, NINCDS, 1960-1961; Assistant Chief, Research Grants Review Branch, DRG, 1959-1960; Acting Chief, Section on Virus Diseases of the CNS, Bureau of Acute Communicable Disease, California State Department of Public Health, 1958; Director, Epidemiology and Biometry Training Grant Program, DRG, 1956-1958; Assistant Chief, Grants and Training Branch, NHI, 1953-1958.

PROFESSIONAL ORGANIZATIONS: American Academy of Neurology; American Association for the Advancement of Science; American

Heart Association, Council on Stroke; American Neurological Association; American Osteopathic Association; Association for Research in Nervous and Mental Disease; Member, Board of Directors, John P. Robarts Research Institute, London, Ontario, Canada; Society for Neuroscience; The American Parkinson Disease Association, Medical Advisory Board; Eisenhower Institute for Stroke Research; United Cerebral Palsy Research & Educational Foundation, Board of Directors; Consultant (Neurology), Pan American Health Organization; Consultant, World Health Organization Program on Neurosciences; World Federation of Neurology; International Brain Research Organization; Commission on Alternative Health Care, U.S. Olympic Council on Sports Medicine.

HONORS, AWARDS: Beta Alpha Epsilon, Biology National Honor Society, NYU; Psi Chi, Psychology National Honor Society, NYU; Sigmi Alpha, Osteopathic Scholarship National Honor Society, College of Osteopathic Medicine; Delta Omega, Public Health National Honor Society, University of California; Doctor of Science (Hon), Kirksville College of Osteopathic Medicine; Doctor of Laws (Hon), New York Institute of Technology; Doctor of Science (Hon), University of New England; Doctoris Honoris Causa, Medical University of Pecs, Hungary; Certificate of Merit, American Neurological Association; 2nd Vice President, American Neurological Association; Silver Star, Purple Heart, U.S. Army; Meritorious Service Medal, Public Health Service; Distinguished Service Medal, U.S. Public Health Service; Founders Day Medal (S.S. Still Medal), University of Osteopathic Medicine and Health Sciences, Des Moines, Iowa.

INSTITUTE BUDGET REQUESTS

Senator WEICKER. Have we received, Jim, the list of all the Institute requests through the process, and your own process, and then OMB, et cetera? Did we get that as we requested?

Dr. WYNGAARDEN. We have it for you, and I can submit it in just a moment.

Senator WEICKER. Fine.

Dr. WYNGAARDEN. The material we have provided shows the chronology by institute and by mechanism. The submissions to the PHS and to the Department were not prepared by institute. The Department's submission provided the estimate by institute to the OMB.

Senator WEICKER. The figure that you have finally been assigned, then, is considerably less, am I correct, than anything that was requested.

Dr. GOLDSTEIN. That is correct, Senator.

[The information follows:]

DHHS - NATIONAL INSTITUTES OF HEALTH
CHRONOLOGY OF THE 1987 BUDGET
(Dollars in thousands)

	1986 1/ COMPARABLE	1987 INST. 2/ EST. TO NIH	1987 NIH EST.2/ 3/ TO PHS	1987 PHS EST. 2/ 3/ TO DHHS	1987 DHHS EST. TO OMB	1987 PRES. 4/ BUDGET
NCI	$1,167,475	$1,463,191			$1,345,058	$1,158,089
NHLBI	800,075	1,029,787			937,597	785,697
NIDR	98,181	122,834			108,740	96,482
NIDDKD	429,687	559,747			482,940	418,971
NINCDS	403,470	577,229			481,904	399,351
NIAID	339,880	493,044			479,327	330,551
NIGMS	486,206	590,016			567,463	471,533
NICHD	307,079	374,148			360,505	309,119
NEI	181,362	225,000			195,429	179,201
NIEHS	188,887	225,654			206,395	187,995
NIA	148,267	194,580			167,582	145,829
NIAMSD	109,788	146,385			126,298	106,733
DRR	290,752	405,968			320,837	234,192
FIC	10,893	14,895			11,931	11,305
NLM	55,273	77,673			59,115	56,408
OD	35,829	42,660			37,757	36,701
B&F	14,259	51,800			18,477	8,000
Total, NIH	5,067,363	6,594,611	$6,415,088	$6,093,456	5,907,355	4,936,157

1/ Reflects proposed sequestration amount of $236,243, a rescission of $76,782, funds held in reserve of $4,056, a carryover in RPGs of $11,247, and comparable transfer of $120,757 in AIDS funding to OASH.

2/ The base used for the development of these submissions was the 1986 President's Budget of $4,852,680.

3/ These submissions were consolidated at the NIH level, no distribution was made by BID.

4/ Excludes $142,990 in AIDS research funding proposed for transfer to OASH.

DHHS - National Institutes of Health
CHRONOLOGY OF THE 1987 BUDGET
(In thousands of dollars)

	1986 COMPARABLE 1/		1987 INSTITUTES' ESTIMATE TO NIH 2/		1987 NIH ESTIMATE TO PHS 2/ 3/	
Research Grants	No.	Amount	No.	Amount	No.	Amount
Research Proj.:						
Noncompeting	12576	$1,967,685	10745	$1,930,169	10745	$1,930,169
Admin. supp.	(435)	16,739	(459)	13,719	(459)	13,719
Competing	5492	867,285	9394	1,573,090	8500	1,392,310
Subtot.,Comp.	5492	867,285	9394	1,573,090	8500	1,392,310
Subtot.,RPG	18068	2,851,709	20139	3,516,978	19245	3,336,198
Research Centers						
Spec/comp.	348	313,383	422	437,363	422	437,363
GCRC	78	86,031	76	93,668	80	97,867
Biotech	61	34,100	58	37,550	58	37,550
LASPR	46	29,041	38	43,037	44	43,037
Gorgas	1	1,913	1	2,000	1	2,173
Subtot. ctrs.	534	464,468	595	613,618	605	617,990
Other Research:						
Careers	1270	76,156	1618	100,952	1618	100,952
Organ sys.	1	957	1	1,000	1	1,042
Clin. ed.	52	4,498	69	7,000	69	7,000
Coop. cl.	245	50,095	358	75,265	358	75,265
BRS	713	91,393	741	114,697	741	114,697
MBRS	92	33,375	89	44,298	89	44,298
Other	530	40,243	785	70,904	795	78,792
Subtotal	2903	296,717	3661	414,116	3671	422,046
Total,RGs	21505	3,612,894	24395	4,544,712	23521	4,376,234
Training						
Indiv.	1473	34,544	1751	47,573	1608	43,654
Instit.	8474	174,733	9453	217,271	8892	204,771
Total	9947	209,277	11204	264,844	10500	248,425
Contracts	1202	330,157	1544	509,287	1544	509,287
Intramural		536,850		674,879		681,062
RM&S		203,463		241,817		241,464
Control		61,131		102,939		102,939
Construct.		8,230		84,000		84,349
Total, IRDs		4,962,002		6,422,478		6,243,780
Nat.Library of Med.		55,273		77,673		76675
O. of the Director		35,829		42,660		42833
Buildings & Fac.		14,259		51,800		51800
TOTAL NIH		5,067,363		6,594,611		6,415,088

1987 Chronology continued:

	1987					
	PHS ESTIMATE TO DEPARTMENT		DHHS ESTIMATE TO OMB		PRESIDENT'S BUDGET 4/	
Research Grants	No.	Amount	No.	Amount	No.	Amount
Research Proj.:						
Noncompeting	12994	$2,324,571	13172	$2,344,571	12785	$2,003,507
Admin. supp.	(406)	12,532	(381)	12,532	(399)	15,200
Competing	6500	1,101,226	6000	1,020,713	5104	784,541
Subtot.,Comp.	6500	1,101,226	6000	1,020,713	5104	784,541
Subtot.,RPG	19494	3,438,329	19172	3,377,816	17889	2,803,248
Research Centers						
Spec/comp.	343	343,439	349	350,164	340	295,403
GCRC	79	95,706	78	98,445	76	86,082
Biotech	54	33,365	61	37,770	60	33,898
LASPR	46	37,110	46	33,252	46	29,905
Gorgas	1	2,173	1	2,151	1	1,934
Subtot. ctrs.	522	511,793	535	521,782	523	447,222
Other Research:						
Careers	1384	83,562	1334	81,861	1270	76,249
Organ sys.	1	1,042	3	2,770	1	800
Clin. ed.	51	5,303	51	5,210	39	2,400
Coop. cl.	298	63,300	303	54,039	256	51,876
BRS	701	104,697	727	100,381	154	32,883
MBRS	81	41,000	79	36,532	92	33,642
Other	590	57,888	547	43,474	489	39,684
Subtotal	3106	356,792	3044	324,267	2301	237,534
Total,RGs	23122	4,306,914	22751	4,223,865	20713	3,488,004
Training						
Indiv.	1412	40,791	1489	35,444	1292	30,630
Instit.	8588	191,341	8663	185,244	7966	167,574
Total	10000	232,132	10152	220,688	9258	198,204
Contracts		434,658	1317	446,021	1192	328,458
Intramural		658,994		612,565		548,357
RM&S		222,082		221,167		210,894
Control		70,244		64,575		61,131
Construct.		40,349		3,125		---
Total, IRDs		5,965,373		5,792,006		4,835,048
Nat.Library of Med.		71.131		59,115		56,408
O. of the Director		41,312		37,757		36,701
Buildings & Fac.		15,640		18,477		8,000
TOTAL NIH		6,093,456		5,907,355		4,936,157

INSTITUTE PROGRAM REDUCTIONS

Senator WEICKER. Where will these cuts, as you see it, if this figure is accepted, come?

Dr. GOLDSTEIN. One, sir, we will have to make across the board, but negotiated, cuts of every active project. Second, we will do everything that we can to protect the individual investigator-initiated research project, as differentiated from centers, and as differentiated from clinical trials.

In fiscal year 1987, although we had planned clinical trials, we will initiate none of them with the budget that has been assigned to us.

NINCDS CLINICAL TRIALS

Senator WEICKER. These clinical trials would have applied to what areas of investigation?

Dr. GOLDSTEIN. First, to stroke. The question we had proposed is that of carotid endarterectomy. Does this, the third most common surgical procedure in the entire United States, do any good in preventing stroke? We have some questions about that. The clinical trial would have evaluated that procedure's efficacy.

In regard to a second study, we have for the first time a chemical which in a pilot study that we have supported, protects persons from remissions and exacerbations of multiple sclerosis. The chemical is a synthetic peptide called copolymer-I. The trial would have cost $2.5 million. We will not be able to launch that trial this year. We will have to postpone it to future years.

There are two new drugs for epilepsy which were to be evaluated in 1987. We will not be able to evaluate any of those new drugs.

There is now a whole new concept of how one might protect the brain against Parkinson's disease. It involves the use of monoamine oxidase inhibitors. We know, because of the results of recent neuroscience research that a street drug, MPTP, causes a Parkinson's disease syndrome. We have now worked out the neurochemistry of the effects of that drug and we know the area of brain vulnerability.

The issue is, can we introduce a chemical which will stop the progress of the pathology. The issue is, in early Parkinson patients, can we give a drug and, as we have begun to learn in chimpanzees, stop the disease from progressing in humans. We would have to postpone the initiation of that study.

ORPHAN DRUG DEVELOPMENT PROGRAM

One of the areas of delay, the impact of which I really can't evaluate at the moment, is our Orphan Drug Development Program for rare diseases such as Tourette syndrome. We have not released an announcement for the development of new drugs in that area. We are waiting to learn more about that.

Senator WEICKER. That is what, I am sorry?

Dr. GOLDSTEIN. The orphan drug program. This is the development

of nonprofitable drugs for rare diseases; the example I used was Tourette syndrome. The decision about this program in 1987 has not yet been made.

Senator WEICKER. How would these be involved in clinical trials?

Dr. GOLDSTEIN. The orphan drug program is a program in which drugs are specifically developed and clinically tested in accordance with the Orphan Drug Act. In each of the previous years, we have dedicated $1 million for the development and testing of these drugs for rare neurological diseases. There is a whole group of diseases of this type, for example, Batten's disease and Tourette syndrome. They are low incidence diseases. For example, tuberous sclerosis is another one of such diseases.

There is a Targeted Research Program, one in which we go out on contract, in order to develop and test the drugs for those very specific rare diseases. Each year, we have invested $1 million in that program. For fiscal year 1987, as of this time, we are holding off on whether to release a solicitation for the development and trial of those drugs.

CLINICAL TRIALS

Senator WEICKER. All of these, I gather, and believe me, I am here as much to get educated as I am to establish appropriations or policy—I gather that a process has preceded this step of the clinical trial to bring you to this point. In other words, this is not the first; there has been something that is its predecessor, that brings you to this point where the next step is the clinical trial.

Dr. GOLDSTEIN. That is right, sir. We have often already gone through two research phases. The FDA describes them as phase I and phase II. Now the definitive clinical trial itself, which is a controlled clinical trial, testing the efficacy of the drugs in those populations which have the disease, as compared to other therapies in order to get the definitive answer.

Senator WEICKER. What happens after the clinical trial?

Dr. GOLDSTEIN. The information then becomes available to the Food and Drug Administration, to determine whether the drug shall or shall not be permitted for general use.

Senator WEICKER. These are pretty significant areas that are at this stage.

Dr. GOLDSTEIN. Yes.

Senator WEICKER. Stroke, multiple sclerosis, epilepsy, Parkinson's, even to a layman like myself, those are pretty well-known afflictions. What you are saying is, if we stick with the $399 million figure, those will not go to clinical trial in fiscal year 1987.

Dr. GOLDSTEIN. That is correct, sir.

Senator WEICKER. What is the total amount that is involved for all of these together?

Dr. GOLDSTEIN. About $14 million in fiscal year 1987.

Senator WEICKER. Jim, is it true that the experience that has been offered here vis-a-vis Dr. Goldstein's budget would apply to other institutes also, other clinical trials?

Dr. WYNGAARDEN. Yes; that is right. The total number of clinical trials that we would start next year is substantially less than in most other years.

Senator WEICKER. I will tell you what I would like. I would appreciate from each one of you a similar recitation of experience as recited from this Institute, those, in other words, that were planned in fiscal year 1987, but will not take place.

Dr. WYNGAARDEN. We have that information.

Senator WEICKER. I can't believe, I just can't believe that if the American public ever knew the dollar amounts being saved in relation to what was supposed to take place as the next step of an orderly process, I don't think that there is an American alive that would go ahead and approve of that.

I will get that from Dr. Wyngaarden.

[The information follows:]

MAJOR NEW CLINICAL TRIALS READY TO BEGIN IN 1987
IF FUNDS WERE AVAILABLE
(Dollars in Thousands)

	First Year Cost	Estimated Total Cost
NCI:		
Biochemical modulation of chemotherapeutic agents in colorectal, breast, stomach, and head and neck cancers	750	2,200
Phase II/III clinical trials using hyperthermia in anatomical sites	600	1,800
Phase I/II trials of additional biological response modifiers	4,000	6,000
Treatment of resectable colorectal hepatic metastases with surgery followed by LAK cells/IL-2 adjuvant immunotherapy	575	1,725
Phase III studies of adoptive immunotherapy of cancer with autologous LAK cells and IL-2	20,000	40,000 1/
Comparison of post operative radiotherapy and adjuvant chemotherapy with chemotherapy, in children with medulloblastoma	100	300
Phase I/II clinical trials of biological response modifiers	2,000	2,500
Treatment of carcinoma of the bladder with hematoporphrin with photoradiation therapy	70	210
Use of TNF in patients with metastatic cancer who have failed conventional therapy	1,150	3,450
Study of radiolabeled monoclonal antibodies to detect sites of Hodgkin's disease involvement	182	546
Subtotal, NCI	29,427	58,731
NHLBI:		
Bypass angioplasty revascularization investigation	1,000	28,600
Dietary intervention in children	700	9,255
Coronary artery bypass graft study	850	29,500
Postmenopausal estrogen and coronary heart disease risk	4,000	12,700
Treatment of pulmonary embolism with tPA	1,000	10,000
Continous positive alveolar pressure treatment of sleep apneas	800	4,000
Penicillin prophylaxis in sickle cell disease	900	1,800
Post-transfusion Non-A, Non-B hepatitis study	1,000	3,215
Deep vein thrombosis diagnosis and treatment	600	10,800
Subtotal, NHLBI	10,850	109,870

1/ Tentative estimate; final cost to be determined when required duration of trial is known.

	First Year Cost	Estimated Total Cost
NIDR:		
Diabetes Control and Complications Trial (DCCT), oral complications	$ 150	$ 300
Clinical evaluations of the relative efficacy and safety of intravenous premedication in dental outpatients	225	425
Subtotal, NIDR	375	725
NIADDK:		
Treatment of short stature with human growth hormone	420	1,400
Nonsurgical (balloons) reduction of stomach capacity in the treatment of morbid obesity	212	464
Postoperative decompression feeding trial	4,785	25,500
Kidney transplantation in children with end-stage renal disease	250	1,000
Expanded nephrologic component of the Diabetes Control and Complications Trial	480	6,650
Controlled clinical trial of hematin therapy for acute prophyric attacks	450	2,500
Subtotal, NIADDK	6,597	37,514
NINCDS:		
Stroke prevention medical surgical carotid stenosis study in asymptomatic patients	3,019	27,394
Stroke prevention by carotid endarterectomy in symptomatic patients	4,176	29,177
Study of cyclosporin A for the management of autoimmune disorders	500	1,575
Monoclonal antibody treatment of multiple sclerosis	500	1,575
Study of monoamine oxidase inhibitors for the treatment of Parkinson's disease	2,000	7,000
Study of orphan products for the treatment of rare movement disorders such as Tourette's syndrome	1,200	3,600
Copolymer 1 in the treatment of multiple sclerosis	2,250	6,750
Efficacy of new antiepileptic drugs in patients with complex partial seizures (two trials)	500	1,500
Subtotal, NINCDS	14,145	78,571
NIAID:		
Monoclonal antibodies in bone marrow transplantation	1,200	4,800
Efficacy trial for rDNA hepatitis B vaccines	150	600
DHPG prophylaxis of cytomegalovirus in bone marrow transplant patients	450	900
Expanded phase I and II trials of antimalarial vaccines	60	135

	First Year Cost	Estimated Total Cost
NIAID: (cont.)		
Efficacy trial for live, attenuated hepatitis A virus vaccine	$ 150	$ 450
Study of different regimens of therapy for systemic candidiasis	300	1,691
Subtotal, NIAID	2,310	8,576
NICHD:		
Effects of growth hormone releasing factors	500	2,000
Nutrition, other factors, and the outcome of pregnancy	150	600
Factors influencing breastfeeding	150	600
Mental Retardation Research Centers network of clinical trials	1,200	6,000
Safety and efficacy of pertussis vaccine	2,200	8,400
Safety and efficacy of Hemophilus influenzae vaccine	500	1,500
Clinical studies with a long-acting spermicidal formulation	150	350
Tests of the use of medications to treat various maternal diseases and the safety and efficacy of various therapeutic agents to stop premature labor	500	2,500
Examination of current treatments in long-term management of bronchiopulmonary dysplasia, and the use of anticonvulsants in the treatment of neonatal seizures	500	2,500
Subtotal, NICHD	5,850	24,450
NEI:		
Central retinal vein occlusion study	1,000	5,000
Treatment of optic neuropathy with steroids	1,500	8,000
Surgical reattachment of the retina in advanced severe retinopathy of prematurity	3,000	12,000
Evaluations of epikeratophakia and keratoprostheses treatment for corneal disorders	1,500	7,000
Surgical vs. laser management of advanced glaucoma	1,000	5,000
Subtotal, NEI	8,000	37,000
NIAMSD:		
Epidermolysis bullosa: efficacy of dilantin and treatment of esophageal strictures	500	2,500
Efficacy of 13-cis retinoic acid in treating keratinizing disorders	1,000	3,000
Subtotal, NIAMSD	1,500	5,500
TOTAL, NIH	79,054	360,937

Senator WEICKER. You are very active because I remember, when I went to visit you at the Institute, one of the areas that you spent a few moments on was Alzheimer's. Would you give us an update on that?

Dr. GOLDSTEIN. Yes, sir; as Dr. Williams, the Director of the National Institute of Aging, discussed with you 2 days ago, we collaborate in a very active research program on Alzheimer's disease. We used to believe that the genetic aspect of the disease affected somewhere between 10 to 20 percent of the population. We now have very good evidence that that was an undercalculation.

Field studies clearly show that in one type of Alzheimer's disease, a genetic determinant occurs in 20 to 30 percent of the population. That is if one brother, or one sister, has the disease, there is a 50-percent probability that the other will develop the disease. We have not yet been able to figure out how to differentiate the genetic aspect of the disease from the disease that occurs in nongenetically linked populations.

The second area of research within the genetic aspect of the disease, is, where is the gene? What does the gene do or not do? It has been reported in the public press now that a gene has been identified which produces a normal protein which travels down the nerve cell. In Alzheimer's disease, that protein may be defective. That is all I know about this particular study. It has not yet been reported in the scientific literature, but will be given as a paper at a scientific meeting in the middle of April. It is by a very competent investigator in Boston. I would anticipate that if he says that he has isolated the gene for the production of this one protein, which may be affecting the whole transport system of the nerve, he has probably got it. But I must await seeing the paper.

What we are studying is what goes on inside the nerve cell itself that is the basis for Alzheimer's disease. One of the theories, and it touches on the genetic influence, is that a material is produced in the cell and is transported down the length of the nerve cell. That material may be an abnormal protein which blocks cell activity. The canal is obstructed and as a result the needed products of the nerve cell can't move down to the end point of the cell, such as a neurotransmitter.

We have evidence microscopically that there is that obstruction to flow. This will be the first evidence to explain why the blockage. That is one of the areas to which we are giving attention.

Another major area in which we are working, in collaboration with our colleagues in the National Institute of Aging, is the issue of which neurotransmitters and hormones are deficient, those that aren't released by the nerve cell and brain.

When you visited with us at NIH, I tried to impress you with the fact that we thought we understood that mechanism. That statement is still true, but it has opened up more questions than it has answered because we have now found several other neurotransmitters that are also deficient and, in fact, may be more important.

What I am really trying to say, sir, as often happens in research, when you get the answer to one question, it opens up two more. We are moving ahead on two major fronts, the neurotransmitter issue, what are the chemicals of the body that are in deficient supply; and, second, within the nerve cell, why?

I don't have much else to report. Let me just summarize it by saying that I think we now have the questions which we didn't have a few years ago. I don't know what the answers are.

CLINICAL TRIAL APPROVALS

Dr. WYNGAARDEN. Mr. Chairman, on the clinical trial issue, we will be starting nine new major clinical trials in 1987 at the request level. Seven of those are in the Cancer Institute, and two of them are in child health. All the other institutes find themselves unable to start major new clinical trials in 1987.

Senator WEICKER. Let me ask this question because you are obviously in a position to pass upon this type of request, and I am not. Very few Members of the Congress, I think, are. I dare say, probably very few members of the Office of Management and Budget. This is obviously something that is in an area requiring technical and professional expertise.

How many of these clinical trials were dispatched at your level, and how many at the OMB level, of the clinical trials?

Dr. WYNGAARDEN. We have that information in dollars and in numbers. The NIH clinical trials are primarily in the contracts line, and some are research projects. In terms of contracts, we requested funds to the Public Health Service for 1,544 at $509 million. The eventual President's budget has funds for 1,192 at $328 million.

Those contracts include many more research efforts besides clinical trials, but that is where the bulk of them would have been. The material I gave Dr. Bongard shows that the institutes submitted a list of $82 million in clinical trials that they would be prepared to start in 1987 were the funds available.

Senator WEICKER. Were most of those approved at your level of review?

Dr. WYNGAARDEN. They are primarily approved at the individual Institute level.

Senator WEICKER. But then don't you have an internal approval at your level before it goes to OMB?

Dr. WYNGAARDEN. Yes; but those are not specifically cited in the submission to OMB; which is by mechanism.

Senator WEICKER. So the cut, in other words, was accomplished at the OMB level.

Dr. WYNGAARDEN. There were cuts from the figure I gave you, which was our estimate to the Public Health Service. There was a cut at the PHS to the Department level from $519 to $434 million. The Department to OMB request was $446 million, actually a little more than that in contracts.

Senator WEICKER. Let's use as the example this Institute.

Dr. WYNGAARDEN. Yes.

Senator WEICKER. These particular clinical trials that are not going to take place, were these trials approved throughout the process until the process got to OMB?

Dr. WYNGAARDEN. The budget submissions were by total mechanism. It would not be precise to say that the ones in that Institute were approved and certain others were not. I think that we have factored in all those that were requested. The number that the 1986 appropriation would have funded was 44, before the deficit reduction and the rescission request; the number for 1987 is 9. So we are down that many from the appropriation in 1986. I don't have the comparable 1985 figures.

Senator WEICKER. In other words, prior to the 1986 4.3-percent reduction, prior to that, we were where?

Dr. WYNGAARDEN. We would have funded 44 major new clinical trials.

Senator WEICKER. This is in this Institute, or across the board?

Dr. WYNGAARDEN. That is across the board. Five of those are in Dr. Goldstein's Institute.

Senator WEICKER. Now, along comes the 1986 automatic cut, now where are we left after that takes place?

Dr. WYNGAARDEN. We have 33 for NIH as a whole, and still 5 in Dr. Goldstein's Institute, but for less money.

Senator WEICKER. OK.

Dr. WYNGAARDEN. Then following the rescission, we are at 31, but still 5 at Dr. Goldstein's Institute for the same amount, in his case, as after the sequestration.

Senator WEICKER. OK.

Dr. WYNGAARDEN. Then the 1987 request level does not contain funds for more than nine clinical trials at NIH as a whole. So we dropped from 44 to 33 to 31 to 9. At that level, the Neurology Institute would be unable to fund any of its previously identified trials.

The five funded in 1986 would be continued, but no new major starts would occur in 1987 in that case.

SCIENCE BUDGETARY EVALUATIONS

Senator WEICKER. Is there somebody that you deal with at OMB who, in a professional sense, in other words, is the equivalent of you or any of your directors?

Dr. WYNGAARDEN. The dealings with OMB are at the Department level. I have not dealt with them myself.

Senator WEICKER. Do you mean at the HHS level, the Secretary's level?

Dr. WYNGAARDEN. I report to the Assistant Secretary, and he reports to the Secretary. The Assistant Secretary of Budget and Management, on behalf of the Secretary, deals with OMB.

Senator WEICKER. Is there somebody who—you, obviously, have no dialog with OMB.

Dr. WYNGAARDEN. No; I do not.

Senator WEICKER. Is there anybody from the Assistant Secretary's Office here in the room?

Mr. BELDON. I am Bill Beldon from the Secretary's Office for the Budget.

Senator WEICKER. In your dealings with OMB, is there somebody that deals with the area of NIH who is professionally equipped to do so?

Mr. BELDON. They are budget analysts, they are not scientists.

Senator WEICKER. That is my question.

Mr. BELDON. They are budget analysts, and they are not scientists. The only scientist in the whole process, I think, at the time that they deal with their budget overview, they involve the Office of Science and Technology as sort of an oversight group.

Senator WEICKER. You have answered my question, and I find that shocking. I find that shocking.

HEAD AND SPINAL CORD INJURY

Two areas that you might touch upon very briefly, Dr. Goldstein, are the head injury and the spinal cord injury areas, what do we hear there that is encouraging?

Dr. GOLDSTEIN. I hope your office staff gave this recent review to you; if not, I will send you another copy. We have just published a review of the entire field of head and spinal cord injury research, not from a patient services viewpoint, but from a research viewpoint.

There are two issues which are really similar in both areas of research. First, we now know quite conclusively that the first 4 hours after either a head injury or a spinal cord injury are the critical times. The horse is out of the barn after that. Namely, the primary damage is done within that 4 hours. Those nerve cells, which have been contused—they are rarely injured directly—it is rarely a bullet, or something of that type—it is usually a physical force to the exterior of the skull and spinal column. Within 4 hours, those nerve cells in the brain or in the spinal cord decide whether they will die or attempt to regenerate, and by regenerate, I mean send out new nerve cell processes for those that have been damaged.

The issue is what happens in those 4 hours that dictates that result. There is a great deal of attention that is being given to that problem, to the biochemical processes in the microenvironment. A great deal of it has to do with surrounding cells that we didn't give appropriate attention to previously, and they are called the glia. Glia, as you know, is the Greek word for glue. In the past, all of these cells around the nerve cell in the brain and the spinal cord, were thought of as only a skeleton. We now know that they are also very active metabolically.

We know, to use a technical phrase, that they are a potassium sink, that is where the potassium goes from the microenvironment of nerve cells. We have very preliminary, but good evidence that those glia cells make important metabolic decisions, and that we have been looking under the wrong streetlight to find out what happened in those 4 hours

by looking only at nerve cells. It is those surrounding cells that influence the determination of nerve cell metabolic processes. We are hard at work on this aspect.

The second major issue is the one I was talking about before, restitution of function. What controls whether the nerve cell regrows, and second, where is the code that determines what connections may be made?

After all, when we were born, there was a code that told the nerve cell where to go. Where is the code? Is it still there, and can we regulate it? These describe the second major area of neurobiological research on head and spinal cord injury.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. I have other questions for response to the record, and also on behalf of the other Senators.

Incidentally, this set of figures has been the most legitimate. Last Monday, we had the 44, 33, 31, and 9, and the ones that applied to this particular institute. Could you also give me a list, as I got from Dr. Goldstein, in one or two words, the nature of each trial that will not take place, that is, Parkinson's, that type of a list.

Dr. WYNGAARDEN. That is the list there.

Senator WEICKER. Then that covers that.

Thank you very much, Dr. Goldstein, we appreciate it.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

GRAMM-RUDMAN

Question. The budget cuts that may be forced by Gramm-Rudman are supposed to be equally applied by program as identified by the appropriations bill and its report. How much direction and flexibility should the Director of a research Institute have in order to minimize the indiscriminate impact of across-the-board cuts?

Answer. Effective and responsible management of a complex research program which includes both extramural research support and productive intramural research activities requires insight as to the scientific opportunities available and the way to take advantage of the new approaches to the difficult research questions posed by human disease. In the neurological and communicative disorders, the range of diseases and disorders is extensive and the consequent research activities are very wide in scope. Only at the operational level of the Institute director can one expect to find the intimate knowledge and detailed understanding of what is needed to accomplish that mission and how to do it most efficiently and effectively. Hence, in my opinion, the director of a research institute like NINCDS should have the discretion to use all approaches and mechanisms flexibly within broad policy guidelines to accomplish the mission of the Institute.

VALUE OF CLINICAL TRIALS
IDENTIFICATION OF INEFFECTIVE SURGICAL PROCEDURE

Question. In your opening statement, you told us that a recently completed clinical trial on the surgical treatment of arterial blockage showed the procedure to be less safe and no more effective than non-invasive medical therapy. This surgical procedure costs about $15,000, am I correct?

Answer. You are correct, the surgical procedure, including diagnosis and hospital costs, usually costs $15,000 per patient.

Question. How much is spent each year on this procedure?

Answer. It is conservatively estimated that 30 to 40 million dollars are spent each year in health care costs on extracranial/intracranial (EC/IC) bypass procedures; this is based on the estimate that there are 2,000 operations performed annually.

Question. How much was spent on this clinical trial?

Answer. The EC/IC bypass clinical trial cost eight million dollars and was conducted over a period of nine years.

Question. I would say the return on investment speaks for itself.

Answer. You are correct, the investment has already paid for itself, in that half the patients who were entered into the study as eligible for the surgical procedure were, in fact, not operated upon. However, the major impact will be seen over the course of

the next several years as a result of the dissemination of the information and discontinuation of the procedure.

Question. Do you have any other evaluations of clinical procedures ready to go?

Answer. Yes, there are currently nine new clinical trials that could not be funded in 1987.

Question. Are you requesting enough funding in FY 1987 to proceed with these trials?

Answer. No, there are not sufficent funds in the President's Budget to support these new clinical trials in 1987.

Question. Please provide this Committee with a complete list of clinical trials that in your professional judgement should begin, along with their cost.

Answer. The following new clinical trials could be initiated in 1987. The total 1987 estimate for these trials is $14,145,000.

Stroke prevention by surgical carotid endarterectomy in asymptomatic patients - FY 1987 estimate: $3,019,000.

Stroke prevention by surgical carotid endarterectomy in symptomatic patients - FY 1987 estimate: $4,176,000.

Study of Cyclosporin A in the management of autoimmune disorders - FY 1987 estimate: $500,000.

Study of monoclonal antibody for the treatment of multiple sclerosis - FY 1987 estimate: $500,000.

Study of monoamine oxidase (MAO) inhibitors for the treatment of Parkinson's disease - FY 1987 estimate: $2,000,000.

Study of orphan products for the treatment of rare movement disorders such as Tourette's syndrome - FY 1987 estimate: $1,200,000.

Study of Copolymer 1 in the treatment of multiple sclerosis - FY 1987 estimate: $2,250,000.

Two new studies of the efficacy of new antiepileptic drugs in patients with complex partial seizures - FY 1987 estimate: $500,000.

NEW TECHNIQUE LEADS TO COST SAVINGS
GUILLAIN-BARRE SYNDROME

Question. I understand that you have had some very positive results from a clinical trial for Guillain-Barre Syndrome. Can you briefly describe this treatment breakthrough?

Answer. A clinical trial of a treatment called

"plasmapheresis", which removes abnormal or toxic substances from the blood, showed that the treatment reduces the length of time patients remain on a respirator by approximately 11 days and reduces the time required for patients to recover the ability to walk by 30-90 days.

Question. Also--since this is a budget hearing--how much did the clinical trial cost?

Answer. The total cost was $911,898.

Question. How much will this treatment save in a one-year period?

Answer. Based on an estimated 2,500 Guillain-Barre patients per year, the use of plasmapheresis could save nearly 28 million dollars in hospital costs resulting from reduced time in intensive care units and shorter hospitalization.

POLIO - LATENT EFFECTS

Question. The findings in your recent report on post-polio syndrome indicate that the reason for muscle weakness and pain is not well understood. Are you planning to intensify your research efforts in this area?

Answer. Recent studies of the nerve fibers of patients with post-polio syndrome suggest that there is a failure of the neurons to maintain the nerve sprouts which had formed to replace destroyed nerves. This process appears to result in a type of premature aging of the nerve. Further basic studies on the ability of nerves to change, and on nerve growth and maintenance, will be required before the processes involved in the cause(s) of post-polio syndrome are fully understood. Such studies are in progress with high priority because they are also fundamental to understanding a wide variety of neurological disorders as well as the post-polio syndrome. Clinical research will emphasize more precise characterization of the disease to identify the factors which distinguish those patients who suffer progressive loss of motor function from those in whom the disease is more benign and to develop methods for prevention and therapy.

Question. In your professional judgement, what level of funding will you need to pursue this problem?

Answer. For Fiscal Year 1987, research opportunities in the area of post-polio syndrome could be explored at a level of approximately $500,000, which includes $100,000 in the Intramural Research Program, and research grant support in the amount of $400,000.

Question. How much are you requesting for this research in the FY 1987 budget?

Answer. The 1987 estimate is $109,000.

Question. Is there any hope that you can offer the 70,000 people suffering from post-polio syndrome?

Answer. Patients suffering from post-polio syndrome can be reassured that the disorder represents neither a reinfection with the polio virus nor the development of amyotrophic lateral sclerosis; also that the symptoms progress very slowly. The ultimate hope for a reversal or halt to the development of post-polio syndrome will lie in the clinical application to this specific syndrome of the information previously acquired from basic studies of the spinal cord and neuromuscular systems as a basis for identifying methods of clinical therapy.

Question. How close are you to finding a cure or therapy which would relieve the pain of the 70,000 people suffering from post-polio syndrome?

Answer. Although pain is not always associated with post-polio syndrome, when it is present it may be difficult to treat. Pain of muscular origin at times responds to drugs which diminish excess activity from the central nervous system, whereas pain originating in joints may respond to non-steroidal anti-inflamatory agents. Occasionally narcotic analgesics are necessary, but these are generally avoided because of the dangers of addiction. Inasmuch as post-polio syndrome is very poorly understood, even clinically, there are, at present, no good leads to either a cure or effective therapy. Consequently, in FY 87 NINCDS will focus research efforts on attempting to understand the basic processes responsible for this syndrome. Such information should lead to the rational development of cures or a therapy, not only for pain but for other symptoms of post-polio syndrome.

JAVITS CENTERS

Question. What progress has been made in awarding the Jacob K. Javits Centers of Excellence in Neuroscience Research?

Answer. This program was initiated in Fiscal Year 1985; four Javits Centers of Excellence were awarded in September, 1985.

Question. How many centers are now in operation and how many more are planned?

Answer. The four Centers of Excellence awarded in Fiscal Year 1985 were each given a commitment for four additional years of support. Those centers are therefore expected to remain active until Fiscal Year 1990. No awards of additional Centers of Excellence are currently planned.

Question. What effect will the possible budget constraints have on Centers already operating?

Answer. In line with our current practice of negotiating commitments downward, we expect that, when the second year of support for each of the four active centers is awarded in September 1986, we will reduce the commitments by an average of 5%.

Question. What effect will the possible budget constraints have on awarding of new Center grants?

Answer. Our projected budget will preclude the awarding of additional Jacob K. Javits Centers of Excellence in Neuroscience either in Fiscal Year 1986 or Fiscal Year 1987.

Question. Can you describe what these Centers are working on?

Answer. The Javits Center at Rockefeller University is headed by Nobel laureate Dr. Gerald M. Edelman, who is directing a team studying the coordination of neural cell interactions. The investigators are addressing several problems in developmental neurobiology including neural degeneration and regeneration, synapse formation, and the formation, function and dysfunction of sensory circuitry.

Dr. Pasko Rakic at the Javits Center at Yale is working on the anatomy, chemistry, and physiology of the developing primate brain. In several related projects, the investigators are mapping out the sequence of steps by which the brain achieves its mature architecture and connections. Findings from this Center should be applicable to our understanding of children's developmental disabilities such as autism, mental retardation, and learning disabilities.

At Washington University in St. Louis, Dr. Gerald D. Fischbach and his associates are studying the formation of synaptic connections and the degree to which these connections change over time in adult animals. New knowledge about normal development of nerve cell connections is expected to lead to a better understanding of abnormal development, in which synaptic connections either fail to form properly, or degenerate prematurely.

Dr. Stanley B. Prusiner, at the University of California in San Francisco, heads a Javits Center research program which addresses the molecular nature of an agent which causes degenerative neurological disease. The agent closely resembles the infectious agent associated with two human dementing disorders, kuru and Creutzfeldt-Jacob disease, which are uniformly fatal.

Question. Are any of them involved in Alzheimer's disease related research?

Answer. The Center at San Francisco is devoted to understanding the causal agent of certain degenerative neurological disorders which have pathological similarities to Alzheimer's disease and have been considered useful models for Alzheimer's disease.

GENETICALLY RELATED NEUROLOGICAL DISEASE

Question. In your opening statement, you mention that many neurological disorders have a genetic component. Given the advances in the understanding of genetics and genetic engineering, are we making any real progress in these areas of neurological disease?

Answer. Significant advances are being made which will greatly aid our efforts to understand, prevent, and cure these neurological disorders. The actual genes responsible for some neurogenetic diseases (e.g. the lipidoses) have been identified and the metabolic defects which they produce are being probed. The region on specific chromosomes for the defective genes responsible for other disorders has been determined, such as Charcot-Marie-Tooth disease, Huntington's disease and Duchenne muscular dystrophy. Animal models for some neurogenetic diseases are being developed. An important new class of neurogenetic diseases caused by recently recognized mechanisms of genetic transmission have been discovered. In these diseases, the abnormal genes are located in the mitrochondria found only in the female ovum and not the male sperm. Examples of such diseases are Leber's Optic Atrophy and Mitrochondrial Myopathy.

NEUROFIBROMATOSIS

Question. What can you tell us about neurofibromatosis?

Answer. Neurofibromatosis is a common human affliction that occurs in one out of 3,000 live births. It is genetic in origin and is transmitted in autosomal dominant fashion. The main clinical signs are cafe au lait spots on the skin, multiple peripheral nerve tumors or neurofibromas and widespread involvement of the skeleton. Neurofibromas can develop in all parts of the body. Central nervous system tumors also occur in 15-20% of the patients, and these, as well as the neurofibromas, can become malignant. Manifestations vary greatly, even within families, but the disease is generally associated with significant mortality and morbidity.

Question. How much are we spending for research on this disease?

Answer. In 1985, the NINCDS supported $3,542,000 for neurofibromatosis related research. The 1986 estimate is $3,623,000 and the 1987 estimate is $3,585,000.

Question. Are there any new or experimental therapies on the horizon?

Answer. At present there are no new or experimental therapies for neurofibromatosis being evaluated at this time. However, it is anticipated that various lines of basic research investigation in this disease will lead to clinical therapies.

HUNTINGTON'S DISEASE

Question. What can you tell us about Huntington's disease?

Answer. Huntington's disease (HD) is a dominant genetic disorder. The discovery of a marker for Huntington's disease has led to the localization of the HD gene on the short arm of chromosome number 4, bringing closer the time when the gene itself, and its products, will be defined. This discovery has also opened up several new research opportunities. Of particular importance

will be studies to understand the variable age of onset of the disorder and the development of prenatal and pre-symptomatic tests for the disease.

Question. How much are we spending for research on this disease?

Answer. In 1985, the NINCDS level of support was $17,357,000 for research related to Huntington's disease. The 1986 estimate is $17,751,000 and $17,563,000 is estimated for 1987.

Question. Are there any new or experimental therapies on the horizon?

Answer. Yes. At present, there are palliative treatments that calm the patient or modify the uncontrolled movements. Studies are underway to test treatments which may slow the underlying neuronal degeneration. The therapies of the future may include gene transfer or substitution, or replacement of specific gene products.

SPINAL CORD INJURY

Question. Dr. Goldstein, what can you tell us about research advances in the area of spinal cord injury?

Answer. Recent research in the areas of spinal cord injury and regeneration of injured nervous tissue have included several new advances: induction of chemical substances no longer present in the adult nervous system that encourage regeneration, defining and manipulating specific receptors on target nerve cells to be able to turn them on, and implanting specific nerve cells into the injured spinal cord in order to encourage regeneration. Clinical investigators are well along on a controlled clinical trial which is investigating the pharmacological manipulation of the acutely injured spinal cord. They are also achieving a better understanding of the cause of scar formation after spinal cord injury and the methods by which scar formation may be minimized. Finally, trophic substances capable of stimulating neurons to regenerate are being carefully investigated and hold promise for the future.

Question. How much are you requesting in your FY 1987 budget for research in this area?

Answer. The 1987 budget estimate is $21,767,000 for spinal cord injury and regeneration research.

Question. In your professional judgement, how much should we be spending?

Answer. In my professional judgement we could invest an additional 20 million dollars on research in this important area.

ALZHEIMER'S

Question. I recognize that the National Institute on Aging has a large research program for Alzheimer's disease. What are you doing in this area?

Answer. NINCDS conducts and supports extensive research in Alzheimer's disease using the latest technology, such as Positron Emission Tomography (PET), to understand the fundamental metabolic and anatomical changes that accompany the progressive, irreversible deterioration of brain function and its possible causes, and to develop new radiological criteria for early recognition of Alzheimer's disease. Areas of intense research emphasis in NINCDS are studies of the biological basis of the disease including the modern approaches to the pathology and chemistry of the disease, "natural" cell death and death due to viral infections and toxins, and the genetic basis for predisposition to Alzheimer's disease. The Institute also supports studies that will lead to more refined diagnostic and prognostic tools, information regarding the natural history of the disorder and clinical-pathological correlations.

Question. How much has been budgeted for FY 1987 compared to FY 1985 and FY 1986?

Answer. The 1987 estimate for Alzheimer's disease research is $13,117,000 compared to $13,117,000 in 1986 and $12,826,000 in 1985.

Question. Is there anything new to report about Alzheimers?

Answer. Research in Alzheimer's disease is progressing in a step-wise encouraging fashion. Progress is being made in understanding the epidemiology of the disease, its possible cause, and the chemical changes which occur. The following are a few of the recent observations made by NINCDS-supported investigators. The largest case-control study of risk factors in Alzheimer's disease has been completed by a team of American and Italian scientists. They have found that individuals whose siblings have any form of dementia may be 11 times more likely to develop Alzheimer's disease; head trauma and maternal age may be factors which predispose to the disease; and that the family history of Down's syndrome, previous thyroid disease, exposure to aluminum, allergies, previous surgical procedures, habits of smoking or drinking wine, or certain personality traits are not risk factors. Investigators have shown that the incidence of Alzheimer's disease in blacks and whites is similar. Yet another study revealed that in certain families with high rates of Alzheimer's disease, there is evidence of an autosomal dominant pattern of inheritance. The prion, the putative infectious agent of the animal disease scrapie, has been found to have a fibrous composition that resembles certain pathological formations in the brains of Alzheimer's patients.

Studies of the chemical pathology that accompanies the neurofibrillary tangles and neuritic plaques characteristic of Alzheimer's disease reveal that two species of proteins, MAP II and tau, present in normal neurons, are highly modified in Alzheimer's disease. The human gene for the tau protein, a component of the tangle, has very recently been identified and cloned. Very recently, it has been reported that the amount of corticotrophin releasing factor (CRF) in the Alzheimer brain is diminished, while receptors for CRF are increased. Thus, new insights into Alzheimer's disease continue to be derived from NINCDS supported research which open possibilities for intervention in the disease.

TRAUMATIC HEAD INJURY

Question. I understand that head injury research is a high priority within your Institute. Head injury research on primates was terminated at the University of Pennsylvania in October 1985 because of questionable treatment of the animals involved. What effect will this action have on head injury research in general?

Answer. Head injury research has been and remains a high priority of the NINCDS. While primate head injury research was terminated at the University of Pennsylvania in October 1985, a great deal of valuable information had already been derived from earlier experiments. The investigators were already in the process of reducing the number of primate experiments and were seeking additional approaches to answer important questions at a cellular and molecular level. Other head injury researchers have also benefited from these experiments and are now able to take these observations and apply them to additional model systems. However, no model system can entirely simulate the complex physiological events observed in primates.

Question. What can be done in this area using non-animal models such as computers?

Answer. While computers are extraordinarily useful tools for analyzing data and comparing results, the extremely complex physiological and pharmacological interrelationships that exist in the living animal or human brain cannot be well simulated. Only when the consequences of severe injury to nervous tissue can be appropriately quantified can such data be entered into computers and used for additional modeling. Some limited success with relatively simplistic systems has already been achieved; however, at this time only the brain of a vertebrate animal can simulate to a reasonable degree the human brain's reaction to trauma.

Question. Can you describe for us how past head injury research has helped in improving the recent treatment of traumatically head injured patients?

Answer. Past head injury research has helped in improving the recent treatment of head injured patients through a better understanding of increased intracranial pressure, blood flow and metabolism in injured and normal brain, and the clinical interactions of various forms of therapy in the injured brain. Epidemiological research has identified head injury as occurring in over 400,000 patients per year, and they are most frequently young men aged 15 to 35. Further investigation has indicated that the types and site of specific brain lesions control outcome for both morbidity and mortality of these head injured individuals. The correlation between specific findings on computer tomography (CT) scanning and the chances of survival, the methods of management of increased intracranial pressure through pharmacological manipulation, the specificity of therapy for the different causes of increased intracranial pressure, and the concept of diffuse axonal injury as one of the pivotal findings in injured nervous tissue have all been major contributions from head injury research. Finally, management of the metabolic imbalances that occur in head-injured patients, the cause and effects of coma, and the value of

prompt surgical intervention in certain cases have all resulted in improved survival for these desperately ill individuals.

AIDS

Question. You have mentioned that scientists supported by your Institute are doing research on the effects of AIDS on the brain. Are you requesting specific funding in the FY 1987 budget to support this work or are you reprogramming these funds from other activities?

Answer. All AIDS funds in 1987 are requested by the Office of the Assistant Secretary for Health (OASH) for subsequent reimbursement to the NINCDS. Within these funds, we have requested an additional $155,000 to support continuation of this research in FY 1987. This additional funding is to pursue the new finding of an increase in adenosine deaminase in erythrocytes of patients with AIDS. Conceivably, the finding of the increased enzyme levels could lead to a supplemental or confirmatory diagnostic test for AIDS. Also, the enzyme test may enable clinicians to monitor the effects of treatment on AIDS patients.

Question. How much will be spent on this research in FY 1987?

Answer. We anticipate receiving $1,575,000 in reimbursements from OASH for AIDS research in FY 1987, of which $158,000 is for extramural research on AIDS dementia, found in a majority of AIDS patients.

Question. In your professional judgement how much should you be spending?

Answer. We have learned much since the FY 1987 request was first developed. New problems and research opportunities have been developed over the last 3 - 6 months. In Fiscal Year 1987, the opportunity for AIDS research, particularly AIDS dementia should increase. In my professional judgment an additional $3 million could be wisely spent, making a program total of $4,575,000.

NEW TREATMENT FOR THE DEAF

Question. I have been reading about a promising development called a cochlear implant. What is a cochlear implant?

Answer. A cochlear implant is a neural prosthetic device that delivers electrical stimuli to the auditory nerve. The purpose of the implant is to provide an awareness of sound and to facilitate communication for the deaf.

Question. What is its significance for the two million deaf persons in this country?

Answer. The significance of the cochlear implant for a portion of the two million deaf persons is the potential to provide a major improvement in listening and speaking abilities.

Question. How far along are you in its development?

Answer. Two single-channel cochlear implants have been

approved by the Food and Drug Administration for adults. A new generation of multi-channel cochlear implants are in various states of pre-market clinical evaluation. A need remains for specialized cochlear implants for children to accomodate growth patterns, and for new types of auditory prostheses for individuals who may not benefit from cochlear implants.

Question. Will it require a clinical trial?

Answer. A pilot trial is in progress with a limited number of patients. A full scale trial may be required; however if the pilot data demonstrate one implant to be superior to all others, a full scale trial may not be needed.

Question. If so, what will this trial cost?

Answer. The estimated cost of a multi-center clinical trial is one million dollars a year for each of five years.

MULTIPLE SCLEROSIS

Question. Dr. Goldstein, your opening statement mentions recent advances in the understanding and treatment of multiple sclerosis. What did you spend on multiple sclerosis research in FY 1985?

Answer. The 1985 level of support for multiple sclerosis and related research was $27,173,000.

Question. What is your budget for FY 1986?

Answer. The 1986 estimate for multiple sclerosis and related research is $27,791,000.

Question. What are you planning to spend in FY 1987?

Answer. The 1987 budget estimate is $27,496,000.

Question. In your professional judgment, what should be spent to take full advantage of the new research opportunities that you just discussed?

Answer. In my professional judgement, $31,500,000 could be used to take full advantage of the new research opportunities for the understanding and treatment of MS. As evidence regarding promising treatments accumulates, additional funds could be needed to carry out the appropriate clinical trials.

IMPACT OF BUDGET REDUCTION

Question. The President's budget proposal for FY 1987 reduces your budget by $32,511,000 under FY 1986 appropriated levels. Gramm-Rudman-Hollings, if triggered, could reduce your budget even further--maybe by as much as 20 percent. I've known this would reduce the number of grants, possibly the size of grants, centers, training, etc., etc. Can you give us some idea of the impact of these reductions on the kinds of research that would be stopped or lost?

Answer. Were further reductions in the FY 1987 budget for NINCDS triggered by Gramm-Rudman-Hollings, all programs supported by the Institute would be affected. After careful review of scientific opportunities and current achievements in the areas of the Institute's responsibility hard decisions would have to be made. Some activities might have to be eliminated, others seriously curtailed. Such decisions would be made only after careful consideration of the scientific and policy guidance from our National Advisory Council. The bedrock of our research program has been and would continue to be investigator initiated research conducted in our intramural research laboratories and in extramural research institutions, and the research training of gifted young persons in the neurological and communicative disorders.

Question. What impact might this have on the health of our citizens five and ten years down the road?

Answer. Investment in biomedical research and research training in the neurological and communicative disorders is a long term endeavor. Today's young investigators in training will provide the scientific bases for advances in the health of our citizens in the future. Curtailment of current research efforts will delay that process and no doubt influence career decisions and thus may have a double impact in slowing research and reducing the pool of investigators capable of making such advances.

Question. Can you discuss your contingency plans if these massive budget cuts should come to pass?

Answer. We have not developed a contigency plan in the event that the sequestration provisions of the Deficit Reduction Act are triggered in Fiscal Year 1987. The budget request for the Institute is consistent with the President's overall policy of submitting a budget within the deficit targets of the Act. Therefore, the sequestration process would not be required.

Question. If the automatic provisions of Gramm-Rudman-Hollings are triggered in FY 1987, your Institute may well have its budget reduced by 20-25%. Have you prepared a contingency plan in the event Gramm-Rudman-Hollings becomes reality? If so, please send a copy of your plans to this Committee.

Answer. A contingency plan has not been prepared.

Question. If cuts of this magnitude become reality, how will they be distributed, by intramural vs. extramural programs?

Answer. If cuts of this nature were required, certainly all elements of the Institute s programs would be affected. In some cases selected programs might have to be eliminated. A careful evaluation of all programs would be required before such decisions could be made. However, to the extent possible, elimination of programs would be avoided.

Question. For the peer review system, would number of site visits be reduced?

Answer. The number of site visits would have to be among the elements considered for reduction.

Question. Would travel to NIH to study section meetings be affected?

Answer. Scientific peer review of grant applications through the study sections is an essential element of the grant review, approval, award process. Travel to study section meetings would be among the last of our administrative expenses which we would consider for reduction.

Question. Would NIH employees have to be furloughed?

Answer. Every effort would be made to avoid staff furloughs. However, depending on the extent of any cuts which might occur, reduction of staff through attrition or furloughs might become necessary

Question. What major programs would have to be cut back?

Answer. At a 20-25 percent reduction, all activities of the Institute would be affected including extramural support of research, intramural research and administrative and management costs.

Question. Please list the research programs of the highest priority that should not be cut and why.

Answer. NINCDS will continue to give highest priority to investigator-initiated research grants which explore the fundamental principles governing the organization and function of the nervous system because our history teaches us that these are the studies which have the greatest likelihood for payoff. Rapid advances have come in neuroscience when new methodologies have been introduced; hence, the current expansion of molecular biological approaches to the nervous system is a high priority area, important in clincial as well as basic neurobiology. Because we are convinced that application of basic knowledge to clinical problems is critical, our research training programs for development of clinician investigators expert in the biological bases of disease will remain a high priority. Our priority setting will continue to be guided by the principles of support for excellence and taking advantage of scientific opportunities in the neurosciences.

Questions Submitted by Senator William Proxmire

CAROTID ENDARTERECTOMY

Question. Dr. Goldstein, in your prepared statement you say you are preparing to evaluate one of the most commonly performed surgical procedures in the United States--carotid endarterectomy for the prevention of stroke. How much does the procedure cost?

Answer. It is estimated that the cost of carotid endarterectomy is approximately $15,000 per patient including diagnosis and hospitalization.

Question. How many times is it performed each year?

Answer. Approximately 120,000 carotid endarterectomies are performed each year in civilian hospitals according to estimates from the National Center for Health Statistics.

Question. How long has this operation been in use?

Answer. The carotid endarterectomy operation was first performed in the mid-1950s. However, during the past decade, improved and less hazardous diagnostic techniques have become available and refinements have been made in the surgical approach itself. This has resulted in the identification of more patients with carotid narrowing and a more refined operative approach, leading to a rapid escalation in the number of patients on whom the procedure has been performed.

Question. Why did you choose this particular procedure for evaluation at this time?

Answer. Carotid endarterectomy has been identified for evaluation in a clinical trial because no scientifically acceptable study of the effectiveness of the procedure has been done. There are reports of unexpectedly high rates of surgical complications and death, and intense debate that the procedure might not be as effective in preventing strokes as has been hoped. There is also some evidence that medical care alone may reduce stroke incidence without the added risk of surgery. The results of the recently published EC/IC bypass clinical trial has sensitized the neurological and surgical communities to the need for applying modern clinical trial methodology to unproven therapies.

Question. When will the evaluation be completed?

Answer. A clinical trial to evaluate the efficacy of carotid endarterectomy will require eight years from the time research begins. This amount of time is required because several thousand patients must be carefully evaluated, entered into the study, and observed for an average of five years in order to determine if those who underwent carotid endarterectomy were protected against stroke.

BRAIN ARTERY BYPASS

Question. Dr. Goldstein, in your prepared remarks you point out that you now know a widely used neurosurgical procedure costing an average of $15,000 and intended to direct blood past obstructed brain arteries "is no more effective--and much less safe--than available medical therapy for preventing stroke." How many such operations are performed in an average year?

Answer. Approximately 2,000 extracranial/intracranial or EC/IC bypass procedures are performed each year in the United States.

Question. Has there been a sharp drop-off in the use of this procedure since the publication of these findings?

Answer. While it is too early for hard data concerning the decrease in EC/IC bypass operations, informal discussion with neurosurgeons has indicated a marked decrease in the number

performed. The major impact of the results of this study can be expected to become apparent during the course of this next year.

OTHER SENSORY DISORDERS

Question. Your 1986 budget for biological basis reseach into "other sensory disorders" is also far below your initial estimate. Last year you projected costs of $16,925,000. This year you have re-estimated those expenditures downward to $14,623,000 after sequestration. Can you tell us why?

Answer. The estimate of the amount of research support for each of the research areas is updated yearly after the previous year's actual level of support is known. In the case of sensory disorder research, the past trends indicate that the level of biological basis research support is not increasing as fast as several of the other research areas. However, this decrease for sensory disorder research is offset by a corresponding increase for clinical research in this area.

NERVOUS SYSTEM FUNCTION

Question. Last year's justifications showed expenditures of $1,910,000 for clinical research into "nervous system normal function" in 1986. Your current budget for "nervous system function" in 1986 is $6,227,000, a more than three-fold increase. Can you tell us why you have tripled your commitment in this area?

Answer. The increase for nervous system normal function reflects the recently added capability of the Institute's new research analysis coding system to code areas such as the training programs and the neural prosthesis program to more specific disorder categories. Since a large proportion of training is in the basic neuroscience areas and we can now classify the basic nerve research aspects of the neural prosthesis program, the funds for these activities are now included in "nervous system function."

PROJECT CONTRACTS

Question. Last year's justifications indicated you would spend $14,230,000 on project contracts in 1986. Despite a Congressional increase in your total budget request your current 1986 project contract budget is only $12,539,000. What contracts have you decided to delete from your budget?

Answer. The budget reflects a decrease of contracts in the areas of hearing and deafness, spinal cord injury, and neural prosthesis clinical developments.

Question. Why have you deleted them?

Answer. The 1986 appropriation for research and development contracts was $13,102,000. It was necessary to delete three contracts for $563,000 in order to reach the sequestration level of $12,539,000.

STAFFING

Question. Last year's justifications indicate that you expected to pay for 749 total compensable workyears in 1985 and 742 in 1986. This year's justifications indicate you had only 698 compensable workyears in 1985 and expect only 700 in 1986 as well as 1987. Why do your current workyear estimates fall so far short of last year's estimates?

Answer. The Institute had a larger than expected turnover of staff in 1985 and experienced difficulties in recruiting replacement staff. During the fiscal year, employment limitations were imposed on the Institute which restricted the Institute to two replacements for every three losses.

NEUROENDOCRINE STUDIES

Question. In last year's justifications you indicated you planned to spend $16,310,000 on neuroendocrine studies under your biological basis research program. Your current estimate for such studies is only $14,501,000 after sequestration, despite a significant increase in your budget request. Can you tell us why you have reduced funding in this area below your initial estimate?

Answer. As in the case of sensory disorder research, the past trends indicate that the level of biological basis research support for neuroendocrine studies is not increasing as fast as several of the other research areas. It should also be noted that the amount of support for each of the various disorder areas is determined by the competitive scientific merit ranking of approved applications.

AIDS

Question. Dr. Goldstein, on page 335 of your justifications you point out that 40 percent of AIDS patients develop brain lesions and "humans having antibodies to AIDS virus without clinical AIDS symptoms frequently carry the virus in their brain, and some of them have a neurological disease." Can you tell us what percentage of those that carry the virus but have not contracted AIDS have a neurological disease?

Answer. We do not yet know what percentage of individuals who carry the AIDS virus have a neurological disorder but not AIDS. This question is being investigated in a well defined group of individuals at risk for AIDS.

Question. Is it possible to say whether or not neurological disease in non-AIDS patients who carry the virus is AIDS virus related?

Answer. At this time, we do not know the answer to the question. Children and adults with a neurological disease who carry the AIDS virus must be studied in order to determine whether or not the neurological signs and symptoms are due to an opportunistic infection or some other cause. In the absence of another identifiable cause, a neurological illness with characteristic cognitive, motor, and behavioral disturbances, or peripheral nerve dysfunction in an individual harboring the AIDS virus or antibodies to the virus is presumed to be due to the AIDS virus.

NATIONAL EYE INSTITUTE

STATEMENT OF DR. CARL KUPFER, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

EDWARD McMANUS, DEPUTY DIRECTOR, NATIONAL EYE INSTITUTE

PREPARED STATEMENT

Senator WEICKER. Next we have the National Eye Institute. Dr. Kupfer, please go ahead and introduce your colleagues, and proceed with a synopsis. Your statement in its entirety will be included in the record, and then we will get to the questions.

[The statement follows:]

Statement of Dr. Carl Kupfer

One of every twenty Americans is visually impaired. This means eleven million people--men and women, senior citizens and children, blacks and whites--have to endure the effects of a permanent visual disability. But the burden is not theirs alone. Professional care and special services for people with eye problems cost our nation an estimated $16 billion a year.

Among the most serious of these eye problems are diseases affecting the retina. If this delicate tissue lining the inside of the eye is damaged, visual impairment, and even blindness, may result. Diabetes is a common cause of retinal destruction, and over a period of years it can cause a series of harmful changes that culminate in profound visual loss. But even when the visual impairment is more subtle, the diabetic patient's quality of life can be drastically altered as vision becomes just blurred enough to prohibit reading or driving a car. The National Eye Institute (NEI) supports research aimed at overcoming the broad spectrum of diabetes-induced ocular problems which eventually affect up to 40 percent of our Nation's 10 to 11 million diabetics.

This past year, the NEI had exciting news for our diabetic citizens. The first results to emerge from the Early Treatment Diabetic Retinopathy Study (ETDRS) yielded information that could be of immediate benefit to many of those still in the early stages of diabetic eye disease. The results showed that focal treatment with a laser can halt or even reverse the relatively mild reduction in visual acuity caused by macular edema. The objective of focal laser treatment is to coagulate tissue that is leaking fluid, causing retinal swelling and blurring of vision. In this national collaborative study involving eye care centers in 15 states, half of the eyes with macular edema underwent laser therapy initially, and half did not. After three years, only 12 percent of eyes in the treated group had lost a significant amount of visual acuity, whereas 24 percent of those in the untreated group had done so. In other words, laser photocoagulation cut in half the risk of visual loss in these patients.

To benefit from laser therapy, however, people with diabetes must have regular eye examinations to find out if this potentially sight-saving treatment is needed. The public health implications of this are enormous. Undoubtedly, the number of diabetics who are eligible for, and seek, some type of laser treatment to preserve their eyesight will increase. On the other hand, we are now able to prevent visual loss and disability in more diabetics. The net savings to society from successful application of this technique for macular edema alone amounts to nearly $100 million a year.

This year, there was important news also for the few diabetics who may someday face one of the most devastating events in the progression of diabetic retinopathy--a severe vitreous hemorrhage. When this occurs, the vitreous gel filling the center of the eyeball becomes clouded with blood. Permanent visual loss or blindness may result. In the past, surgeons had to make a decision about surgery in these patients without knowing whether it was better to wait and see if the hemorrhage cleared up on its own, or to risk a delicate operation to remove the blood and scar tissue from the center of the eye.

These two approaches--immediate versus deferred surgery--to management of a vitreous hemorrhage which has caused serious loss of vision were compared in an NEI-supported clinical trial. The investigators found that 25 percent of eyes which underwent early surgery ended up with relatively good visual acuity, while only 15 percent of those in the deferred treatment group did so. For patients who had juvenile onset diabetes, the beneficial effect of early treatment was even more remarkable. In these eyes, three times as many in the early treatment group achieved good results (36 percent compared to 12 percent in the deferred treatment group). The conclusion: surgery performed soon after a serious hemorrhage can improve the chances for recovery of good vision in selected patients.

As you can see from these two clinical trials--and from our original Diabetic Retinopathy Study--we have accomplished a great deal in recent years when it comes to determining the most successful treatment strategies for a broad range of diabetic eye problems. In the future, we hope we will also be able to offer diabetics an effective means of preventing altogether the ocular complications of this disease. A major clinical trial is now underway to determine whether the drug sorbinil can slow or block the development of diabetes-associated eye and nerve damage. When this Sorbinil Retinopathy Trial was initiated, you may recall that I said one of the most gratifying aspects of the study is that it represents the culmination of years of basic research in the laboratories of the National Eye Institute. From pioneering work delineating the role an enzyme called aldose reductase plays in the development of diabetic complications, we have progressed to clinical evaluation of a drug that inhibits this enzyme and holds promise of interrupting the disease process. I am pleased to report that during the past year, patient recruitment was nearly completed. The enrollment goal of 600 patients will be reached soon, and the study will proceed towards its long-term scientific goal. If sorbinil proves effective, this drug and ones like it will revolutionize the management of diabetes and dramatically improve the outlook for people with this disease.

Even further in the future, there is a possibility of using treatments derived from recombinant DNA technology to protect diabetics from complications. In molecular genetic research going on right now in the NEI's laboratories, investigators are attempting to locate and isolate the actual genes which dictate the production of aldose reductase. Finding a way to interfere with the activity of these genes would give us an alternate method for blocking the onset of diabetes-associated tissue damage.

Molecular genetics is also being employed in the study of hereditary retinal disorders such as the retinitis pigmentosas. Scientists are trying to obtain more information about the underlying causes of this family of diseases in the expectation that this knowledge will make it possible to halt or prevent the process of retinal cell breakdown that leads to blindness. This year, NEI grantees took a significant step toward this goal. They confirmed and refined earlier estimates of the location of the gene that causes one specific type of retinitis pigmentosa. And now the genes responsible for other types are being sought. We hope that this research will clear the way to direct study of the defective genes, resulting in a much better understanding of the disease process and, eventually, gene therapy for the disorder.

We are also continuing to conduct and support basic research on

the neurobiology of vision, a field which has proven to be one of the most scientifically fertile areas in the whole rapidly developing discipline of neurobiology. Within the last year, studies sponsored by the NEI have led to a better understanding of the function of retinal photoreceptors--the critically important nerve cells that give the visual system its capacity to detect light. For a long time we have known that these cells work by absorbing incoming light rays and then firing off electrical impulses in response. But the intermediate steps in this process, called transduction, have been unclear. There is a pressing need to further our understanding of visual transduction because malfunctions in this process can lead to irreversible visual loss. We anticipate that new knowledge in this area will bring us closer to comprehending the many sight-impairing diseases marked by abnormalities in the retina's responses to light. But in addition, research on transduction in retinal cells is expected to yield information about normal and abnormal neural signal transduction in all sensory systems of the body. Because the retina has proved to be such a good model in this regard, scientists in many other fields have recently turned their attention to the visual system, joining forces with vision scientists in trying to unravel the mysteries of transduction in retinal photoreceptors.

At the beginning of my presentation today, I described how two NEI-supported national collaborative studies had led to improved treatment of diabetic eye disease. Now I would like to tell you about a new clinical trial which may someday provide the basis for better management of retinopathy of prematurity, a disease that blinds many of the very smallest premature infants. The study will evaluate cryotherapy as a treatment for infants whose disease has progressed far enough that it threatens to destroy the retina. AltHough there is evidence to suggest cryosurgery might halt potentially blinding retinal changes, doctors caring for these babies need to know with certainty whether the technique is beneficial, what the risks are, and whether it is possible to tell in advance which babies will benefit from the procedure.

Before concluding my remarks today, I would like to mention the important role program planning plays in helping the National Eye Institute to decide whether to sponsor research like the two new clinical trials described above. Thanks to our ongoing program planning efforts, we are able to pinpoint where research is needed most, where the scientific opportunities are greatest, and where we would expect to receive the biggest return on our investment in terms of improving the prevention and treatment of blinding eye diseases. We are currently updating our 5-year plan, which covers the years 1983-1987, to take into account recent scientific advances and fresh opportunities in various areas of vision research. We will be sure to transmit a copy of this document to the Committee as soon as it is completed, probably in April. Through this planning process, we will maintain the careful but flexible investment strategy that has helped to make our program so productive thus far. In this way, I believe the National Eye Institute will be able to maintain the momentum of scientific achievements that have been such a striking feature of vision research over the past decade.

Mr. Chairman, the 1987 budget request for the National Eye Institute is $179,201,000.

I will be happy to answer any questions.

Biography of Dr. Carl Kupfer

February 9, 1928. New York, New York.
Education: A.B., Yale University, 1945-48. M.D., The Johns Hopkins Medical School, 1952 Certified. American Board of Ophthalmology, 1958.
Professional History: Internship and Assistant Residency, Wilmer Eye Institute, Johns Hopkins Hospital, 1952-1954. Laboratory Assistant, Biostatistics, Johns Hopkins School of Medicine, 1953-58. Research Fellow in Ophthalmology, Wilmer Eye Institute, Johns Hopkins Hospital, 1957-58. Research Fellow in Ophthalmology, Harvard Medical School, 1958-60. Instructor in Ophthalmology, Harvard Medical School, 1960-62. Assistant Professor of Ophthalmology, Harvard Medical School, 1962-1966. Professor and Chairman in Ophthalmology, University of Washington School of Medicine; Research Affiliate, University of Washington Primate Center, 1966-70.
Professional Organizations: American Physiological Society, Association for Research in Vision and Ophthalmology, American Academy of Ophthalmology, American Ophthalmological Society, Pan American Ophthalmological Society
Honors and Awards: Editorial Board, Investigative Ophthalmology, 1969-1977. Editorial Board, American Journal of Ophthalmology, 1971 to present. Member, Scientific Advisory Committee, Fight for Sight, Inc., 1971 to present. The Secretary's Special Citation, Department of Health, Education, and Welfare, April 1972. The Superior Service Award, Department of Health, Education,and Welfare, May 1974. Ticho Memorial Lecture, September 1974. Migel Medal, American Foundation for the Blind, October 28, 1976. Public Service Award in Ophthalmology, American Academy of Ophthalmology and Otolaryngology, October 1977. Speaker, Glenn A. Fry Award Lecture, American Academy of Optometry, December 1981. Senior Executive Service Bonus, Department of Health and Human Services, 1981. Johns Hopkins Society of Scholars, Johns Hopkins University, May 1982. Honorary Doctor of Science Degree, Scheie Eye Institute, University of Pennsylvania, November 1982. Member, Institute of Medicine, January 1983 to present. Speaker, XIV Jules Stein Lecture, Los Angeles, California, April 1983. Recipient, Special Award of Honor, The Juvenile Diabetes Foundation, June 1983. Recipient, David Rumbough Memorial Scientific Award, The Juvenile Diabetes Foundation, June 1983. Recipient, Presidential Rank Award of Meritorious Executives, 1983. Lecture, New York Academy of Medicine, New York, N.Y., March 1984. Bowman Lecture, The Ophthalmological Society of the United Kingdom, London, England, April 1984. Recipient, The Lighthouse Pisart Vision Award, October 1984. Lecture, Howard University Hospital, Washington, D.C., December 1984. Member, Board of Trustees, Helen Keller International Inc., 1975 to present. Coordinator for USA, US-Japan Collaborative Agreement in Vision Research, 1976-1982. Organizer, Oxford Assembly, International Agency for the Prevention of Blindness, (IAPB) 1978. Coordinator for USA, Priority Area "Eye Diseases," US-USSR Program for Health Cooperation, 1978-1981. Speaker, General Assembly of the World Council for the Welfare of the Blind, Antwerp, August 1979. Director, WHO Collaborating Center for the Prevention of Blindness, National Eye Institute, Bethesda, MD, 1979. President, IAPB, 1982 to present.

SUMMARY STATEMENT

Dr. KUPFER. Yes, sir. With me is Mr. McManus, the Deputy Director of the National Eye Institute.

I would like to make a very brief statement, if I may.

Eleven million people have to endure the effects of a permanent visual disability, but the burden is not theirs alone. Professional care and special services for people with eye problems cost our Nation an estimated $16 billion a year.

Research supported by the National Eye Institute can help to reduce these economic and social costs. Today, I would like to tell you about one of the National Eye Institute's most cost-effective research programs, our Retinal Disease Program.

Diseases affecting the retina of the eye are among the most serious of all eye problems, and one of the most common causes of retinal disease is diabetes. Over a period of years, it can cause a series of harmful changes that culminate in profound visual loss. Even when the visual impairment is more subtle, the diabetic patient's quality of life can be drastically altered as vision becomes so blurred, the individual cannot read or drive an automobile.

Research supported by the National Eye Institute is aimed at overcoming the broad spectrum of diabetes-induced ocular problems, which eventually affect up to 40 percent of our Nation's 10 to 11 million diabetics.

This past year, the National Eye Institute had exciting news for diabetics. The first results to emerge from the early treatment diabetic retinopathy study, yielded information that could be of immediate benefit to many of those still in the early stages of diabetic eye disease.

The results show that it is possible to halt or even reverse the effects of diabetic macula edema, a condition which can cause blurring and serious visual loss. Investigators found that treatment with a laser cut in half their patients' risk of losing vision.

The condition being treated in this study and the laser technique employed are quite distinct from those involved in the diabetic retinopathy study, the results of which were reported to this committee several years ago. But taken together the results of these two clinical trials provide a compelling reason for diabetics to have regular eye examinations—to find out if they have a condition requiring some form of laser treatment to preserve their vision.

If the findings from these two studies are applied in this way, and the patients treated appropriately, the net savings to society could total more than $500 million a year.

Mr. Chairman, I thank you for the opportunity to appear before you, and I would be happy to answer any questions. The request for fiscal year 1987 budget is $179,201,000.

CLINICAL TRIALS

Senator WEICKER. How did you fare in this clinical trial business?

Dr. KUPFER. We had suggested five and these were not included in the budget.

Senator WEICKER. Would you please tell us what those were?

Dr. KUPFER. Central vein occlusion, a condition in which the vein supplying the retina becomes occluded, often results in blindness. We have been successful in a recent clinical trial in treating some forms of branch vein occlusion even when one of the branches of the retinal vein, becomes clogged. Now we would like to extend these studies to see whether we can be equally effective in treating complete occlusion of the central retinal vein. That would be the first trial.

The second is designed to evaluate steroids in the treatment of optic neuropathy. This is a hotly debated area because we don't really know whether loss of vision due to inflammation of the optic nerve will or will not be helped by high doses of steroids. To determine whether this treatment is effective or not, one needs to do a clinical trial.

The third clinical trial is directed toward the increasing problem of severe retinopathy of prematurity. Infants who are born premature have a propensity to develop abnormal vessels in the retina, and the retina can very often become detached. In this clinical trial surgical reattachment of the retina in these infants would be assessed.

The fourth is an evaluation of a new technique called epikeratophakia. One can actually change the refractive properties of the cornea by taking pieces of eye bank cornea, freezing them, lathing them with different curvatures, and then grafting them onto the surface of the patient's cornea—thereby changing the optical properties of the cornea. This is a technique which may have great promise, but it has to be evaluated in a scientific way.

Finally, a comparison of surgical versus laser management of advanced intractable glaucoma is the fifth clinical trial that has been proposed.

CORNEAL INFECTIONS

Senator WEICKER. I understand that the herpes simplex virus causes about 500,000 cases of sight-threatening eye infections every year. You have reported that a new drug therapy has been developed to treat this condition. Would you care to comment on that?

Dr. KUPFER. Yes, sir; this is very much in the same view as information provided to you by Dr. Fauci, Director of the National Institute of Allergy and Infectious Diseases. You will recall that he was talking about herpetic encephalitis, and the two drugs that were used were adenine arabinoside—vidarabine—and acyclovir. In point of fact, these two drugs were first evaluated in the treatment of herpes disease in the cornea. The cornea provides a good model for studying drugs that affect viruses.

As a matter of fact, the first successful antiviral drug was tested in the cornea. It is easy to see the infection, and it is easy to see if the infection is going to respond in a very short period of time.

One thing we have learned, however, is that once the virus penetrates into the interior of the cornea, it no longer seems to be reached by the antiviral agents. So we are now using recombinant DNA techniques to learn how the virus replicates and develop new approaches to controlling it.

LASER TREATMENT

Senator WEICKER. In the course of these studies that relate to whether or not a particular procedure is successful or not, we are sort of 1 year further down the track since we discussed it the last time, laser surgery vis-a-vis cataracts.

Dr. KUPFER. Yes, sir.

Senator WEICKER. Is that pretty well accepted now as being a successful treatment, or are there any doubts about that?

Dr. KUPFER. The laser per se really doesn't play a very important role in cataract surgery as much as it does in retinal problems such as diabetic macula edema, aging related maculapathy—which I reported on last year—and in the treatment of certain forms of glaucoma.

Use of the laser on cataracts is really limited to the need to open the capsule, if the capsule becomes clouded following surgical removal of the lens. The present way of removing the cataract is to remove the contents of the lens, but leave the capsule intact. Sometimes, the capsule becomes opaque and then the laser is used to make an opening. So that is the limited utilization of the laser in cataract.

But as I said, the laser is invaluable to the retinal surgeon in the treatment of retinal disease, and to the glaucoma surgeon.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. I do have further questions for answer to the record. I also have a leadership meeting coming up at noon, so I will have to move along. But I thank you very much.

Let me ask one question before you leave. In the matter of the clinical trial, Jim, were there any at NEI that were on the original list before it dropped down to zero here?

The track record, in other words, for Dr. Goldstein was five, five, five, zero. All along the line, were there five planned also?

Dr. WYNGAARDEN. I have given my table to Dr. Bongard, but we have another. They had one in 1986.

Senator WEICKER. They had one all along.

Dr. WYNGAARDEN. They had five planned for 1987, none of which will be conducted.

Senator WEICKER. Thank you very much, Dr. Goldstein.

Dr. GOLDSTEIN. Thank you, sir.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

VISUAL IMPAIRMENT

Question: I understand that 10 million of our citizens suffer from visual impairment that cannot be corrected by eyeglasses. Of these 10 million people an additional 1.5 million are considered so severely impaired that they cannot read ordinary newsprint. In your professional judgment, does the FY 1987 budget request provide enough funding to pursue all significant research opportunities in the area of eye research?

Answer: All of the highest priority activities will be supported with funds included in the 1987 budget request.

Question: Do you have an estimate of the cost of vision impairment to the nation's economy?

Answer: Based on a recent survey by a health enconomist of both the direct costs (those associated with medical, hospital, and other health and institutional care) and indirect costs (such as those associated with days lost from work or housekeeping) of visual disorders and disabilities, we estimate that the current annual cost of eye disorders and visual impairment in the United States is approximately $16 billion.

REHABILITATION OF VISUAL IMPAIRMENT

Question: What kind of support does the Eye Institute provide for research into the rehabilitation of the visually impaired?

Answer: The National Eye Institute provides research grant support for investigator-initiated projects on the rehabilitation of visually impaired persons. Support in 1985 for rehabilitation research was approximately one million dollars. This includes five projects supported through our small business innovative research mechanism. During the past year the NEI issued a special request for applications on research to provide a profile of visual function in low vision patients. This special program elicited 20 applications and will probably result in 6 new awards during 1986. Topic areas addressed by projects in this area include the development of reading aids, visual requirements for mobility, control of eye movements in retinal degeneration, and the ability to recognize human faces.

Question: In this age of highly sophisticated technology, is anything on the horizon that would improve the sight of individuals who are impaired?

Answer: Applications of electronic technologies are leading to devices that will improve the quality of life of visually impaired persons. In particular, personal computer technology is being applied to the development of reading aids that magnify or present in modified format ordinary reading materials. This is sometimes combined with synthesized speech that can substitute for cumbersome braille output. Optical character recognition technology is also being used to convert printed information to tactile or verbal output. There are also mobility aids under development that relay

information on features of the environment, thus making it easier for a visually impaired person to move about unassisted.

Question: Are we providing enough resources for research in this area?

Answer: Yes, we are providing sufficient resources for the most promising research proposals in this area.

HERPES/BLINDNESS

Question: I understand that the herpes simplex virus causes about 500,000 sight-threatening eye infections each year. You have reported that a new drug therapy has been developed to treat this condition. Please bring us up to date on this new drug, and tell us if it will be effective in preventing the blindness caused by herpes virus.

Answer: The agent that you refer to is vidarabine, also known as Ara-A. It is the second antiviral drug ever developed (idoxuridine was the first) and has been available for several years for the treatment of epithelial herpes infections of the eye. Vidarabine is particularly useful in treating those patients suffering from herpes keratitis who are sensitive to idoxuridine or are infected with a herpes strain which is resistant to treatment with the latter drug.

However, one limitation of vidarabine is that it is relatively insoluble and must be administered as an ointment. Another concern is that, like idoxuridine, vidarabine can eventually give rise to drug-resistant strains of the virus. For these reasons, the NEI has continued to support and encourage research to discover new drugs for the treatment of ocular herpes. For example, an antiviral agent, trifluorothymidine, which does not produce resistant mutants in vitro appears to be a particularly promising treatment modality for ocular herpes in the near future--particularly since it is highly soluble and can be applied as drops rather than as an ointment. However, vidarabine is expected to be a mainstay of ocular herpes therapy for some time to come.

Question: Can you estimate how much the Federal Government spent in developing this drug?

Answer: I would estimate that approximately $800,000 of Federal funds have been expended in the development of vidarabine.

CYCLOSPORINE AND EYE DISEASE

Question: I have been told that the immunosuppressant drug, cyclosporine, has been proven effective in preventing certain forms of blindness. Please review this information and tell us how close we are to making this drug available to the public.

Answer: The earliest evidence of the clinical worth of cyclosporine was obtained outside the field of vision research, in studies which showed the drug could improve the success rate of transplant operations involving the kidney and other vital organs. In such cases, the drug is of value because it prevents the immune system from reacting to the newly transplanted tissue and destroying

it. These findings on cyclosporine attracted the attention of National Eye Institute scientists, who theorized that the drug might also hold promise in the treatment of several forms of uveitis. In this disease, delicate tissues of the inner eye become inflamed and may eventually be destroyed. Studies conducted at the NEI have shown that many cases of uveitis are autoimmune in origin. That is, they arise because the immune system has mistaken eye tissues for foreign invaders and has mounted an attack against them. Because uveitis often can't be controlled by the corticosteroids and other drugs that are generally used to treat it, the NEI recognized that there was a great need to evaluate cyclosporine as a possible agent for suppressing the abnormal immune activity that underlies many cases of this disease.

At the NEI, studies conducted with animals have shown that cyclosporine can completely block the development of autoimmune uveitis and prevent blinding eye damage. Studies involving patients are still in progress. Also, NEI investigators contributed to the development of a multicenter clinical trial recently conducted in Japan which showed that cyclosporine is effective in the treatment of Behcet's disease. This is a painful autoimmune disorder that includes uveitis as one of its components.

However, it is also important to evaluate the safety of cyclosporine as a treatment for uveitis. The NEI investigators have been carefully monitoring patients for signs of any adverse drug effects. Particular attention is being paid to subtle changes in kidney function that appear to accompany long-term use of cyclosporine. We expect that it will be a few years before vision scientists have obtained enough information to weigh the benefits of the drug against its risks, and determine whether it is best used independently or in combination with more traditional treatments. When that knowledge has been obtained, it will be possible to effectively address the issue of making the drug more widely available for the treatment of uveitis.

Question: Are we providing enough funds to support a maximum effort in this area?

Answer: Yes. I believe that the funds requested are sufficient to maintain our present pace of progress in this area.

CLINICAL TRIALS

Question: In your opening statement, you reviewed for us the importance of using the clinical trial to test the effectiveness of newly developed therapies, and to make them available to our citizens. How many new therapies or research advances are now awaiting clinical trial?

Answer: We are aware of five new multicenter clinical trials that are in an advanced stage of planning. A number of other new clinical trials are being actively discussed within the research community.

Question: How many of those waiting for clinical trial will actually be done in FY 1987?

Answer: No new clinical trials will be supported in 1987.

Question: In your professional judgment, how many more should be done in FY 1987 and at what additional cost?

Answer: The 1987 cost of five new clinical trials that could be done is $8 million.

Question: Please provide this committee with a list of all clinical trials that are ready to be started, and include the yearly cost of each one.

Answer: The following clinical trials could be started in 1987:

	(In Thousands)	
	1987 Cost	Total Projected Cost
Central Retinal Vein Occlusion Study	$1,000	$5,000
Treatment of Optic Neuropathy with Steroids	1,500	8,000
Surgical Reattachment of the Retina in Advanced Severe Retinopathy of Prematurity	3,000	12,000
Evaluations of Epikeratophakia and Keratoprostheses as Treatments for Corneal Disorders	1,500	7,000
Surgical vs. Laser Management of Advanced Glaucoma	1,000	5,000
Total	8,000	37,000

RESEARCH OPPORTUNITIES VS. BUDGETARY LIMITATION

Question: You have told us of your planning efforts that enable you to choose where research is needed most and where the opportunities are greatest. This is a commendable effort but I expect that these choices are not easily made and that many opportunities are not pursued solely because of budget limitations. What opportunities will be lost or delayed by this year's budget request?

Answer: The following activities in addition to the clinical trials tabulated above will be delayed in 1987:

o Development of new animal models of diabetic retinopathy and other retinal diseases that involve growth of new, abnormal blood vessels. Diabetic retinopathy is the leading cause of visual loss in people during the prime earning years.

o Use of recombinant DNA technology to acquire information needed to improve the treatment of ocular herpesvirus infections and develop a means of preventing recurrences.

o Research to identify the causes of chronic blepharitis and associated corneal conjunctivitis and develop effective treatments.

o Research on the cornea to better understand the physical and biosynthetic factors that play a role in determining the effectiveness and predictability of the various refractive surgical procedures.

o Use of molecular biology and associated techniques to learn more about the lens and develop means of modifying its genetic make-up so as to eventually be able to prevent cataract formation.

o Research to develop non-invasive methods for continuously measuring intraocular pressure. Such tools are required for understanding the cause and progression of glaucoma.

o Application of molecular genetics to the study of glaucomas that occur early in life, in particular primary congenital glaucoma.

o Development of improved treatments for amblyopia that may give the patient a better chance of achieving normal binocular vision.

o Epidemiological studies of risk factors for myopia, clinical trials of treatments for myopia, and research on the influence of refractive and accommodative states on the development of the eye.

PREVENTION

Question: During last year's testimony you informed the Committee that 27% of your research budget was devoted to projects directed toward prevention of eye disease or visual disability. Please give us some examples of research in this area.

Answer: The National Eye Institute is supporting a variety of studies aimed not only at the prevention of diseases of the eye, but also at their serious consequences--visual impairment, disability, and blindness. Some highlights of prevention research supported by the Institute are summarized below:

o A clinical trial, the Early Treatment Diabetic Retinopathy Study, is being conducted to test the effectiveness of argon laser treatment in preventing the worsening of diabetic retinopathy in people whose disease has not progressed far enough to pose an immediate risk of blindness, i.e., those with macular edema, pre-proliferative retinopathy, and mild or moderate proliferative retinopathy.

o A case-control study is being conducted in diabetic patients to identify and evaluate medical and social factors (e.g., family history, smoking habits, beverage consumption) which may be associated with great risk for the development of diabetic retinopathy. Blood specimens from these patients are also being evaluated for systemic and metabolic factors which may play a role in the development of retinopathy. It is expected that this information will allow the evaluation of the predictive value of the risk factors identified.

o The laser doppler technique is a noninvasive means of measuring blood flow rate at selected sites in the retina. It is being used to characterize quantitatively the retinal circulation of selected patients with diabetic retinopathy, to aid in diagnosis, to determine prognosis, and to monitor the effectiveness of therapy in prevention of blindness.

o Oral sorbinil, an inhibitor of the enzyme aldose reductase which has been implicated in the etiology of many complications of diabetes, is being administered in a double-masked randomized clinical trial to diabetics with no or minimal diabetic retinopathy to evaluate its effects on the development and progression of retinopathy.

o The modes of action of two inhibitors of vascular endothelial cell proliferation are being investigated to determine whether they are potentially useful as inhibitors of the blood vessel growth associated with proliferative diabetic retinopathy which leads to visual loss.

o Studies are currently in progress to isolate and characterize aldose reductase messenger RNA and to clone and sequence the aldose reductase gene. Information obtained from these studies may allow the development of methods to selectively inhibit the aldose reductase gene and thereby prevent some of the complications of diabetes.

o A study is being conducted in animal models to determine whether the use of aldose reductase inhibitors can protect against diabetic cataract development, arrest further progress where cataract development has begun, and promote a reparative process.

o Although primary angle-closure glaucoma is a significant cause of visual loss and blindness, the timely administration of appropriate therapy is highly effective in preventing the progression of the disease and loss of vision. A two-center coordinated study is being conducted to determine the natural history of angle-closure in suspect patients (those patients who have the anatomical features that may predispose to the disease) and to evaluate prospectively, present methods for predicting it--provocative tests.

PREVENTION RESEARCH

o A study is being conducted to assess the value of home tonometry (the at-home use of an instrument which measures intraocular pressure) in glaucoma patients and ocular hypertensives (individuals with elevated intraocular pressure who do not have glaucoma but may develop the disease). This study may serve to identify early those ocular hypertensive patients at risk for developing open-angle glaucoma and should enable physicians to prevent or delay glaucomatous damage to the optic nerve by prescribing optimal drug administration schedules to coincide with periods of elevated intraocular pressure.

o The lens protein alterations associated with cataract development are being studied in a number of laboratories. Determination of the molecular bases of these changes may aid in the prevention, retardation, or reversal of cataractogenesis.

o Proteolytic enzyme activity (the breakdown of proteins by enzymes) is being determined in normal and cataractous human lenses. If proteolysis is involved in the development of cataract, the control of this destructive activity may be an alternative target for prevention or retardation of lens opacification.

o Cataracts may result from light-induced oxidation in which toxic products accumulate and damage the lens tissues. Investigations are being conducted of the metabolism and protein synthesis in the lens to delineate the mechanism by which oxidation causes cataract. Researchers are also studying factors, such as vitamin C, vitamin E, and various enzymes which act as antioxidants, in protecting the lens against such oxidative stress.

o In an effort to understand how nutrition may be related to the serious problem of senile cataract--the opacification of the lens which occurs with aging--studies have been conducted on the development of cataracts in animals maintained on diets deficient in tryptophan (an important building block of proteins), vitamin E, and selenium. These studies have indicated that nutritional deficiencies in tryptophan and vitamin E cause development of cataracts in these animals by a mechanism different from that causing cataracts in animals fed a diet deficient in tryptophan alone. Current research also indicates that diets which contain an imbalance of selenium provide additional stress that leads to an increased incidence of cataracts.

o A technique for scanning the lens surface is under development to study the effects of repetitive near-ultraviolet (UV) light exposure on the biochemistry of the lens. Exposure to sunlight and UV light has been implicated in the formation of cataracts, and identification of the biochemical mechanisms involved may ultimately lead to the development of measures to prevent or retard cataract development.

PREVENTION INITIATIVES

o A multicenter randomized controlled clinical trial, the Branch Vein Occlusion Study (BVOS), has documented the natural history of branch vein occlusion and improved the management of its complications.

o Age-related macular degeneration (AMD) affects the macula, a highly specialized portion of the retina which enables sharp central vision. AMD is the leading cause of new cases of blindness in people age 65 and over. One of the major age-related changes in the retinal pigment epithelium is the progressive accumulation of lipofuscin or "age" pigment which is thought to contribute to macular degeneration. Studies are under way using a rat model to study the factors responsible for the accumulation of this pigment. The other major change seen in AMD is progressive photoreceptor degeneration. Research has shown that diets deficient in vitamins A and E, taurine, selenium, and zinc lead to the build-up of oxidative products within the photoreceptors and damage to the photoreceptors in animals. Researchers are trying to determine the efficacy of administering vitamins E and C (because of their

antioxidant properties) to patients who already have severe visual loss in one eye due to AMD; patients will be monitored to see whether the treatment regimen can protect their good eye from visual loss. Other investigators are studying the role of selenium nutrition in AMD and are trying to determine if selenium supplementation can arrest the progression of the disease.

o The effects of intense light exposure in normal rats and a strain with inherited retinal dystrophy are being determined by measuring light-induced changes in the rod outer segment (ROS) and retinal pigment epithelium (RPE) membrane lipids and proteins. Prolonged exposure to high intensity light has been shown to produce photoreceptor damage, whereas dark-rearing retinal dystrophic rats has been shown to decrease the rate of retinal degeneration. The relationship of genetic and nutritional factors to the retinal damage caused by light is also being explored. These studies may lead to a better understanding of hereditary retinal degenerative conditions such as retinitis pigmentosa and may ultimately allow the development of measures to prevent or retard the degenerative process.

o The roles of cyclic nucleotides and protein kinase in normal vision and in retinal degeneration are being examined in animal models and cell culture systems. Abnormalities in the levels of some nucleotides have been measured in animal models with hereditary retinal degenerations and in pigment epithelium and choroid specimens from a patient with hereditary choroideremia. This study should provide information which will allow determination of whether these alterations are a primary cause of the degenerative process or are related secondarily to the degeneration, and therefore, may aid in the development of agents to prevent or slow the degenerative process.

o Gyrate atrophy of the retina and choroid is a rare form of inherited retinal degeneration characterized by elevated levels of the amino acid ornithine in the bloodstream due to an enzyme deficiency. NEI-supported researchers are currently evaluating the therapeutic efficacy of low arginine (an ornithine precursor), low protein diet with supplemental amino acids and monitoring patients for arrest or improvement of their disease.

PREVENTION INITIATIVES

o In the past year the NEI has inaugurated a major clinical trial to evaluate cryotherapy as a method of halting the progression of a blinding disease of low-birth-weight infants (called retinopathy of prematurity) in severely affected children. In this procedure selected sites on the sclera (the white of the eye) are frozen with a cryoprobe in an attempt to alter the underlying retinal tissue to create a barrier that prevents the abnormal growth of blood vessels that threatens to detach the retina.

o Vitamin A deficiency is the leading cause of childhood blindness in developing nations throughout the world. As part of its responsibility to assist in the worldwide effort to prevent blindness, the NEI is funding projects to determine the normal fluxes or movements and metabolism of vitamin A and other nutrients in the retina and retinal pigment epithelium. Other studies are

designed to determine the efficacy of various retinoids (vitamin A analogues) in treating experimental xerophthalmia, a drying of the cornea and conjunctiva associated with vitamin A deficiency, in animal models. Investigations are being conducted of the role of infection and inflammation in the development of keratomalacia, a sight-threatening softening and drying of the cornea resulting from prolonged vitamin A and protein deficiency. The NEI is also collaborating with the National Institute of Nutrition in Hyderabad, India, in operating a clinical research center for nutritional blindness supported by Public Law 480 funds. One of the goals of this center is to define more clearly the factors, in addition to vitamin A deficiency, that increase a child's risk of nutritional blindness, and to evaluate the efficacy of various forms of dietary supplementation.

o Fundamental to the development of more informed pharmacologic approaches to the promotion of the healing process and prevention of vision loss after injury to the ocular surface is an understanding of the mechanisms which regulate the molecular genetic processes in corneal epithelial cells. A study is being conducted to determine whether certain growth regulating factors which have been shown to affect these molecular genetic processes in cultured corneal epithelial cells are operative during the corneal wound repair process.

o A randomized clinical trial is being conducted to determine whether the use of ascorbate (vitamin C) and citrate to treat human eyes which have had moderately severe, severe, or very severe alkali burns can prevent sight-threatening ulceration and perforation of the cornea.

FUNDING FOR PREVENTION

Questions: Will the FY 1987 Budget Request support this level of effort in prevention research?

Answer: The National Eye Institute will obligate approximately 21 percent of the total 1986 and 1987 budgets for research to prevent visual impairment, disability, and blindness.

Question: What are the projects that will be stopped or significantly reduced in size?

Answer: The National Eye Institute will support essentially the same total number of grants in 1986 and 1987, so that it is likely that our total prevention effort will be sustained.

Question: What is the long-range impact of these cutbacks in the area of prevention?

Answer: Although progress in these areas may be delayed as a result of the cutbacks, the effect on any specific prevention category should be minimal.

TRAINING PHYSICIAN SCIENTISTS

Question: In last year's testimony, you stated that the National Eye Institute's research career program had trouble

attracting physician scientists. Do you have any planned or current programs to address this problem?

Answer: In late 1984 NIH and NEI announced the availability of the new Physician Scientist Awards. These awards will provide the opportunity for clinicians to develop into independent investigators, to obtain research experience under the sponsorship of an experienced researcher, and to initiate a research program. Five Physician Scientist Awards were made to investigators in the first full year of the program.

Question: Please describe the impact of the FY 1987 Budget Request on these programs.

Answer: Although the FY 1987 budget will slow the growth of this new program, commitments to awards made in prior years will be honored.

Question: In your professional judgment, how much should you be spending to really address this problem?

Answer: The scope of this program is limited as much by the number of applications as by the availability of funds. However, the initial response was good. We believe the number of applications submitted will increase as this new program becomes more widely known and we will make every effort to continue to fund outstanding applicants.

Question: What else should you be doing?

Answer: At the present time the National Eye Institute staff is actively seeking individuals with a clinical background who would like to broaden their research experience and urging them to apply for the Physician Scientist Award. Also, clinicians are urged to participate in ongoing clinical research projects and then to apply for initial research support from the NEI, either through the conventional Research Project Grant (RO1), the New Investigator Research Award (R23), or the Small Grants for Pilot Projects (RO3). The New Investigator Research Awards and the Small Grants are particularly suited to this purpose because they have been structured to enable people with little research experience to conduct small projects that could be expanded and to foster further development of newly trained laboratory scientists and clinicians for careers as independent investigators in vision research.

CATARACTS

Question: I understand that almost 3 1/2 million people have some form of cataracts, and that this condition is the third leading cause of blindness in this country. How many new cases of blindness due to cataracts occur each year?

Answer: Each year, 850,000 to 900,000 Americans undergo surgery for cataract that has progressed far enough to affect vision. For the great majority of these people, the surgery will restore visual function. But in a few people there will be postoperative complications or other cataract-associated problems that result in lasting visual loss. Also, ophthalmologists

encounter some people who need cataract surgery but decline to have it because of fear of the operation. Because of these factors, at least 4,500 people become blind each year as a result of cataract, and several times as many experience lasting visual loss in one eye.

Question: In FY 1986 Congress appropriated over $14 million for research into cataracts. In your professional judgment, is this level of funding sufficient to take advantage of every significant research opportunity in this area?

Answer: Although the 1986 appropriation does not include funds to take advantage of every significant research opportunity, it is certainly sufficient to pursue the most important initiatives in cataract research.

Question: How much should be spent?

Answer: Based on preliminary results of the Midcourse Evaluation of Vision Research--A National Plan: 1983-1987, the Planning Subcommittee of the National Advisory Eye Council recommended a funding level of $15.5 million for cataract research in 1986.

Question: What is your budget request in FY 1987?

Answer: The 1987 budget request for cataract research is $13,275,000.

CATARACT STUDY

Question: I understand that you recently began a study of 1,500 patients with cataracts in the Boston area. What results are you expecting at the conclusion of this study?

Answer: A major aim of the study is to identify and estimate the importance of various risk factors for senile cataract. Among the factors that will be evaluated as possible predictors of cataract development are nutritional status; dietary history and physical measurements; systemic diseases such as high blood pressure, cardiovascular disorders, and diabetes; ocular factors such as myopia and use of eyeglasses; family history; demographic variables such as sex, education, occupation, and race; environmental factors such as sunlight exposure; and also usage of drugs, tobacco and alcohol. We hope that this analysis will yield a much clearer picture of what factors, separately or in combination with each other, may contribute to the development of cataract. Such information might eventually be used in programs for cataract prevention.

Another aim of the study is to evaluate and improve systems for classifying the severity of different types of cataract. Advances in classification will contribute to the overall progress of research on cataract and will facilitate future studies to evaluate any preventive or therapeutic agents that emerge from basic research.

A third aim of the study is to explore the reasons for the lower frequency of cataract in the United States than in India. It

is hoped that comparison of risk factors from the Boston-area study to those studies in India--where people are at higher risk of cataract and tend to develop it younger than Americans--will yield new clues to the causes of the disease.

Question: Have you requested a budget that will allow you to conduct this study in the best way possible?

Answer: Yes. The additional FY85 funds that the Congress appropriated for the NEI to support clinical trials have made it possible to initiate this study.

GLAUCOMA

Question: You have told this Committee that glaucoma is one of the leading causes of visual impairment in this country, and "may be the leading cause of blindness among black Americans". Yet--you are requesting $1.1 million less than FY 1986 appropriated levels of $15.8 million and will support only two full-time training positions. In your professional judgment, how much funding, and training positions, should be allocated to glaucoma research to take full advantage of presently known research opportunities?

Answer: Our expert consultants in this area estimate that approximately $21 million would be needed to take advantage of all of the research opportunities in the area of glaucoma research and training. As many as six new full-time training positions could be funded at that figure.

GLAUCOMA

Question: Last year you issued a report on Glaucoma Control. Am I correct in stating that early detection of glaucoma is the best way of controlling this disease?

Answer: Because the visual damage caused by glaucoma is irreversible, early detection is essential to the maintenance of good vision. Early detection is certainly an important element in glaucoma control since delayed recognition and care may result in cases of visual loss which could have been prevented. However, a small but significant percentage of people with glaucoma lose vision despite early detection, due to treatment failure. In addition, even the best available screening method does not detect all cases of glaucoma and some cases may go undetected until noticeable loss of visual function has occurred. For this reason, the National Eye Institute has emphasized the support of research on improved early detection of glaucoma and as well as on developing improved methods of treating this disease.

Question: How have you responded to the recommendations put forth in that report?

Answer: The report's recommendations included expansion of research efforts in areas of high program relevance identified in Vision Research--A National Plan: 1983-1987, particularly studies of the epidemiology, etiology, and diagnosis of glaucoma. Laboratory research was encouraged in the areas of 1) understanding the pathogenetic basis of optic nerve damage, 2) new types of treatments, and 3) how to improve patients' use of medications.

A major epidemiologic study is now underway in Baltimore, investigating the prevalence of glaucoma in blacks and whites, and seeking to identify risk factors correlated with the disease. Four smaller risk-factor studies are also in progress. Recently, two studies have suggested that a large percentage of glaucoma patients fail to take their medications as prescribed, either by not using a significant amount of their eyedrops, or by putting them into the eye improperly. The clinical community has been made aware of the need to educate patients on the importance of taking drops properly and on schedule.

A new diagnostic aid, now being tested clinically, will allow patients to measure their own intraocular pressures at intervals during the day and night. This may help clinicians to 1) determine the patient's clinical status more accurately and 2) promptly evaluate the impact of medication changes. Other new approaches to diagnosis involve studies that utilize new non-invasive psychophysical measurements of vision to identify signs which may provide early warning of loss of optic nerve function.

Increased numbers of researchers are now investigating the cell biology, molecular biology, and biochemistry of the ocular tissues involved in glaucoma. One of these is the trabecular meshwork, an area of the eye that is a major contributor to the buildup of intraocular pressure. Another important new study has just begun to investigate the cellular biology of the optic nervehead, in an effort to learn why and how it is damaged when pressure is elevated above normal.

Finally, a new clinical trial of a means of improving the outcome of glaucoma surgery in high-risk eyes has been initiated. Also, a clinical trial testing the efficacy of laser treatment of early glaucoma in comparison to conventional medical treatment is well underway and should begin to yield results in about a year.

Question: What impact will the proposed FY 1987 budget have on your response to the recommendations made concerning glaucoma control?

Answer: Current activities initiated in response to the report will be continued at levels that will assure that the integrity of individual research projects is sustained. We will implement new initiatives as funds permit.

Question: How much more funding would be necessary to implement the suggestions made in that report?

Answer: To implement the suggestions made in the report the Institute would need approximately an additional $6.5 million in 1987.

IMPACT OF BUDGET REDUCTION

Question: The President's Budget proposal for FY 1987 reduces your budget by $15,793,000 under FY 1986 appropriated levels. Gramm-Rudman-Hollings, if triggered, could reduce your budget even

further--maybe by as much as 20 percent. I've known this would reduce the number of grants, possibly the size of grants, centers, training, etc., etc. Can you give use some idea of the impact of these reductions on the kinds of research that would be stopped or lost?

Answer: The President's Budget was developed within overall deficit targets that would preclude the need for sequestration in 1987. If sequestration levels turn out to be as much as 20 percent below the 1987 budget request, all NEI programs would probably be affected to some extent. This would compel us to review all program options in light of the new fiscal situation, and perhaps this review would result in a decision to delay or terminate some activities in each of our major programs.

Question: What impact might this have on the health of our citizens five and ten years down the road?

Answer: It is difficult to know precisely what the long-term effects of these budgetary proposals would be. The substantial cuts to which you refer would certainly limit our ability to sustain the research base and pursue promising new research leads. Eventually, we would expect that this would reduce the likelihood that new and improved means would be developed for treating and preventing eye diseases, because such advances are fostered by research.

Question: Can you discuss your contingency plans if these massive budget cuts should come to pass?

Answer: Since the budget levels contained in the 1987 request were developed to meet the deficit reduction targets of Gramm-Rudman-Hollings, no contingency plans have been made to implement further reductions.

Question: If the automatic provisions of Gramm-Rudman-Hollings are triggered in FY 1987, your Institute may well have its budget reduced by 20-25%. Have you prepared a contingency plan in the event Gramm-Rudman-Hollings becomes reality? If so, please send a copy of your plans to this committee?

Answer: If the current economic projections are accurate, the budget levels in the NEI 1987 request will make it possible to meet the outlays at the levels established in Gramm-Rudman-Hollings.

Question: If cuts of this magnitude become reality, how will they be distributed:

1. Intramural vs. Extramural Programs;
2. Peer Review System;
   Would number of site visits be reduced?
   Would travel to NIH to study section meetings be affected?
3. Would NIH employees have to be furloughed?
4. What major programs would have to be cut back?

Answer: Reductions of the magnitude you mentioned would warrant careful review of all programs, and would possibly require eliminating certain lower priority activities altogether.

Question: Please list the research programs of the highest priority that should not be cut and why?

Answer: In the research areas of high priority identified in Vision Research--A National Plan, support will be continued in order to take advantage of the most promising opportunitites for the discovery of new means to prevent eye disease and visual disability. Included in this category would be basic as well as clinical research, funded by extramural support mechanisms or conducted within the intramural research program. Determinations concerning the level of support for research in each program area will be made in accordance with budgetary factors and the criteria just noted.

Questions Submitted by Senator William Proxmire

COST OF COMPETING PROJECT GRANTS

Question: Dr. Kupfer, on page 119 of your justifications you indicate you plan to support 250 competing project grants in 1987 at an average cost of $135,000, an increase of 10.1 percent in direct costs over 1986. Even with this increase you will be making an 11.6 percent reduction from full recommended levels while you have normally made reductions of only 3 or 4 percent. If we assume that in 1986 you make your normal reductions of 3 or 4 percent, then you plan to cut an added 8 percent or so from each grant, despite the fact that the average grant will receive 10.1 percent more than in 1986. As I calculate it, this means the full recommended direct cost level for an average competing grant in 1987 will be 18.1 percent more than in 1986. Why are grant costs going up so sharply?

Answer: The 1986 budget estimate for competing research project grants is based on the assumption that grant awards will be almost 12 percent below full recommended amounts, rather than at historical levels of 3 or 4%. We estimate that the average recommended total cost of competing research project grants will be $154 thousand in 1987, 9.2 percent more than the comparable 1986 cost of $141 thousand. This increase is due to escalating personnel and indirect costs, more expensive research techniques being used, and the fact that research conducted on grants with relatively higher scientific merit tends to be more expensive.

RADIAL KERATOTOMY

Question: Dr. Kupfer, as you may recall last year we discussed a relatively new procedure known as radial keratotomy, a correction of nearsightedness through surgically making tiny cuts around the cornea of the eye. This is a very expensive alternative to glasses and may have adverse effects on vision. You indicated last year that you were studying the procedure for its safety and efficacy. Have you come up with any interesting findings over the past 12 months regarding the long-term results of the operation?

Answer: I am pleased to share the most recent findings from the Prospective Evaluation of Radial Keratotomy study which the NEI supports. Last September, the study released findings on the effects of radial keratotomy in hundreds of its patients who had undergone the operation two years earlier. These two-year data

confirm earlier reports that radial keratotomy often is effective in correcting nearsightedness. But they also strengthen earlier findings that the outcome of the procedure is variable and cannot be predicted with certainty for an individual patient. For example, in a third of the patients in this study the degree of nearsightedness continued to change for more than a year after surgery. It was not possible to predict which patients would show such changes.

In addition, the results indicate that when radial keratotomy is performed in both eyes of an individual patient, the two eyes may show different outcomes, with one being more strongly corrected than the other. Such a disparity was noted in a fourth of the patients in this study. Also, the study found that when a radial keratotomy did not produce sufficient improvement in vision, a repeat procedure might give unexpected results: Four of the 42 eyes that had reoperations actually became more nearsighted as a result of the second surgery. Finally, in three eyes corneal infections related to radial keratotomy developed more than a year after the surgery.

In view of these two-year findings, the study's investigators are convinced that further evidence will be needed before the safety and efficacy of radial keratotomy can be assessed. The NEI concurs in that belief, and will continue to support research on this procedure.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

STATEMENT OF DR. DAVID P. RALL, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

CHARLES E. LEASURE, JR., EXECUTIVE OFFICER, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

PREPARED STATEMENT

Senator WEICKER. Next we have the outsider from North Carolina, who doesn't share the joys of Washington, DC, like the rest of us. I understand, Dr. Rall, you want me to come and visit you in North Carolina.

Dr. RALL. We would love to see you down there.

Senator WEICKER. You have to realize that because of the senatorial situation, it is probably dangerous territory for me to wander around. [General laughter.]

In any event, the next institute we have is the National Institute of Environmental Health Sciences, Dr. Rall.

Dr. Rall, please go ahead and present your statement, which will be included in its entirety in the record, and you may comment on it as you wish.

[The statement follows:]

STATEMENT OF DR. DAVID P. RALL

The National Institute of Environmental Health Sciences (NIEHS) is celebrating this year the twentieth anniversary since its original founding as the Division of Environmental Health Sciences in 1966. We have come a long way since then.

When we now live with environmental health issues virtually every day, it is easy to forget that in 1966 the country was still reeling from the impact of Rachel Carson's Silent Spring. Twenty years ago, Dr. Irving Selikoff of Mt. Sinai had just published his landmark epidemiological studies of the hazards of asbestos. There was no Environmental Protection Agency; no Clean Water Act; no Clean Air Act, and Superfund was 15 years off. Love Canal was a modest neighborhood in New York, probably never heard of outside the Niagara Falls area. NIEHS was simply a division in the National Institutes of Health (NIH).

Since that time, with the continuing support of the Congress and this Committee in particular, we have:

--Built a cadre of scientists with unique expertise to address environ-mental health problems. At NIEHS, we have built a strong corps of scientific talent which is of worldwide repute, and which can tackle concerns from a variety of perspectives. Centers for research have been established in universities throughout the country, and individual grants and contracts have been used to create a pool of scientific talent and vital scientific information which simply did not exist twenty years ago.

--With this developing expertise, we have studied chemicals with enormous public health impact such as asbestos, lead, DES, dioxin, and PCBs. Today, we are able to estimate not only the carcinogenic potential of a chemical, but in many cases, also its effects on the reproductive, neurologic, and other systems.

Where are we going in the next ten years? Our research programs are changing to take advantage of increases in our knowledge base. We are beginning to understand more about the mechanism of action by which toxins cause disease. We can broaden our inquiry from looking at specific endpoints (carcinogenicity, teratogenicity, etc.) and specific organs of the body to looking at the whole person. We see that potentially toxic chemicals can affect all of the major systems of the body, cardiovascular, nerve, respiratory, even the immune system. These less visible effects are much more far reaching than we originally thought, and it appears that when these chemical toxins interrupt a normal process of one part of the system, they create problems in other parts of the system in ways we do not fully understand. It appears that the body is a complex communications network that cannot function properly when any one major piece is not working correctly.

In order to attack these problems, we have gradually evolved over the years into four major scientific divisions that cover the spectrum of research opportunities. Scientists in our Intramural Research Program (IRP) concentrate on understanding the various ways in which environmental factors enter the body and disrupt its normal functions. Using the latest techniques and equipment, they encompass many scientific disciplines as they attempt to unravel events at the cellular and subcellular level.

The Biometry and Risk Assessment Program (BRAP) utilizes epidemiological studies and mathematical models in conjunction with studies of the underlying biological mechanisms to evaluate the risks

of various chemicals. BRAP also places a great deal of emphasis on the development of methodology useful in the evaluation process.

The Toxicology Research and Testing Program (TRTP) is the core of the National Toxicology Program (NTP) and through its activities provides much of the scientific information used by other regulatory and public health agencies to understand which chemicals may be public health hazards, and what types of efforts must be initiated to prevent or reduce harmful exposures.

And finally, our Extramural Program (EP) funds research and training in numerous disciplines throughout the country. Utilizing investigator initiated research grants and program projects, centers, fellowships, training grants and other mechanisms of support, a cadre of scientists at universities and research centers concentrates on the prevention, diagnosis and treatment of a variety of environmentally induced diseases.

What are some of the most promising areas of research and how are the different parts of our program focusing on them? Scientists in the Intramural Program are concentrating their efforts on understanding the mechanisms by which the environment alters the body's normal functions. The theme underlying their research efforts is based on the fact that the body's functions are fundamentally controlled by complex interactions between basic communication networks. Each of these networks or systems communicates with one another in a moment to moment, reversible fashion in response to the ever-changing set of environmental signals that act upon various parts of the body. When all is working properly, the communicating systems respond in an integrated fashion inducing adjustments in literally every part of the body down to the most minute component of each cell. At times, however, environmental insults overwhelm one or more of the communicating systems such that integration of responses becomes difficult or even impossible, leading to a debilitating disease or in some cases, if the change is irreversible, death.

Recent discoveries have pointed out how complicated these dynamics can be. NIEHS scientists have learned, for example, that man-made toxic agents such as phorbol esters and diethylstibestrol (DES) mimic the actions of many naturally-occurring, growth promoting hormones but in ways that lead to abnormal growth of cells. In intramural studies these chemicals are being used as experimental tools to broaden our understanding of the ways in which some factors increase the sensitivity of biological systems to chemical insults.

Phorbol esters, representing a class of well known tumor promoters, are counterparts to the fatty substances in our bodies that normally serve as mediators of growth-promoting hormones. However, unlike these normal body fats, they are not metabolized or deactivated by the host cell. DES formerly used as a growth stimulant in animal feed, is metabolized. Sometimes, unfortunately, its metabolism leads to the production of powerful agents called free radicals that can alter the structure and function of many cellular constituents, including the DNA. Such findings suggest that alterations of the levels of free radicals may be of potential usefulness for preventing the adverse effects of both man-made toxicants as well as of natural body hormones.

We will be pursuing these areas of investigation during the coming year, and I expect to be able to report our findings to you next year.

Another promising area in which our understanding is rapidly growing is the study of the molecular basis for cancer. In the last few years a family of cancer-causing genes, called oncogenes, has

been uncovered. This discovery has provided tremendous insight into how a cell with altered DNA is promoted to become cancerous. It is believed that these oncogenes have a role in normal cellular growth and differentiation. However, when there is an insult to the DNA by a carcinogen, these oncogenes are activated and begin to produce altered protein products or too much of the normal product.

Drawing on NIEHS' unique capacity for carcinogenic studies in rodent model systems, we have mobilized a research effort aimed at characterizing activated oncogenes and at establishing approaches to utilize this data in analyzing the health risk from exposure to certain classes of chemical carcinogens. Our work to date suggests that oncogene activation in spontaneous tumors is different in some cases from that observed in chemically-induced tumors. This understanding provides a possible approach for substantially increasing the sensitivity of chronic animal tests for detection of carcinogens. This may help identify those cancers caused by chemicals and even some of the chemicals involved.

We are also studying the interplay among oncogenes that may occur in order for a normal cell to be transformed into a malignant one. Such work may eventually allow us to classify carcinogens according to their mechanism of action and further enhance our ability to estimate accurately the risk of cancer in humans exposed to carcinogens.

We continue to test potentially toxic compounds under the heading of the National Toxicology Program. It is a complicated process that does not always come up with the results one would have predicted or hoped for based on the experience we have gained over the years. Chlorinated paraffins, or clorowaxes, for example, had been identified as possible replacements for polychlorinated biphenyls (PCBs). The market for this class of chemicals appears to be increasing: 250,000 tons are produced worldwide each year for use as extreme pressure lubricants, flame retardants and secondary plasticizers. Among the more notable findings that have developed since I last spoke with the Committee is our awareness of the very significant toxicity of the chlorinated paraffins. The structure of this class of compounds is such that we would not have originally expected them to present as serious a hazard as the results of testing indicate. Yet, in fact, under conditions of two-year animal studies there was clear evidence of carcinogenicity.

The immediate and delayed effects of acute inhalation exposure to methyl isocyanate (MIC), the chemical reported to be the primary causative agent in the disaster in Bhopal, India, were studied in rats and mice. At toxic levels, MIC caused severe damage to the respiratory tract but no damage to other organs; however, the lung damage persisted throughout the study. Additional studies showed that there were no or minimal effects on fertility, reproduction, the immune system, and host defense. MIC was not significantly mutagenic in our tests.

On the other hand, there is good news about ephedrine sulfate, a compound that is widely used in nonprescription pharmaceutical preparations such as nose drops, cough syrup, various ointments and suppositories, and for the relief of hemorrhoids. It is also used for the treatment of asthma and other allergic conditions. This compound was nominated for testing by the National Cancer Institute because of its widespread, long-term use. I am pleased to report that testing shows no evidence of carcinogenicity in our systems.

Last year the Committee requested from us a plan of research for studying the health effects of acid rain. That report has been submitted. It points out that acid rain is a complex phenomenon, not a

toxic substance per se, that can result in increased human exposure to air pollutants and toxic metals. As such, any research plan to study the health aspects of this issue must involve a study of those pollutants and metals. NIEHS has been a major supporter of research in these areas.

A few additional areas that would more fully round out our effort in this area were identified at an NIEHS-supported conference. These new initiatives, to be funded extramurally, will involve epidemiologic studies as well as laboratory research into the synergisms and antagonisms among toxic components of acid rain, and into the potential health effects of aluminum.

Our budget request for fiscal year 1987 is $187,995,000. I would be happy to answer your questions.

Biography of Dr. David P. Rall

August 3, 1926. Aurora, Illinois

Education: B.S., North Central College, 1946; M.S. (Pharmacology), Northwestern University, 1948; M.D., Northwestern University School of Medicine, 1951; Ph.D. (Pharmacology), Northwestern University, 1951.

Professional History: 1952-53, Intern, Bellevue Hospital. 1953-58, Scientist, Laboratory of Chemical Pharmacology, National Cancer Institute. 1958-63, Head, Clinical Pharmacology and Experimental Therapeutics Service, General Medicine Branch, National Cancer Institute. 1963-69, Chief, Laboratory of Chemical Pharmacology, National Cancer Institute. 1966-71, Associate Scientific Director for Experimental Therapeutics, National Cancer Institute. 197i-present, Assistant Surgeon General, USPHS.

Professional Organizations: American Association for the Advancement of Science, American Association for Cancer Research, American Public Health Association, American Society for Clinical Investigation, American Society for Pharmacology and Experimental Therapeutics, Society for Occupational and Environmental Health, Society for Risk Analysis, Society of Toxicology.

Honors, Awards: Editorial Board, Proceedings of the Society for Experimental Biology and Medicine, 1962-65. Member, National Institutes of Health Chemotherapy Study Section, 1965-67. PHS Meritorious Service Medal, 1966. Chairman, National Institute of General Medical Science Pharmacology Toxicology Review Committee, 1967-69. Editorial Board, Pharmacological Reviews, 1969-72. Chairman, DHEW Departmental Committee on Drug Research and Regulations, 1970. Associate Editor, Cancer Research, 1970-74. Chairman, OST-CEQ Ad Hoc Committee on Environmental Health Research, 1971-72. Adjunct Professor, University of North Carolina, Chapel Hill, 1972-present. US Coordinator, Environmental Health Program, US-USSR Health Exchange Agreement, 1972-present. Chairman, DHHS Committee to Coordinate Environmental and Related Programs, 1973-1985. Editorial Board, Archives of Environmental Health, 1973-76. Associate Editor, Journal of Toxicology and Environmental Health, 1974-78. DHEW Distinguished Service Medal, 1975. Member, DHEW Secretary's Review Panel on New Drug Regulation, 1975-76. Member, NAS Safe Drinking Water Committee, 1975-1977. Chairman, Committee on Health and Environmental Effects

of Increased Coal Utilization, 1977-78. Member, Institute of Medicine, 1979-present. Editorial Board, American Journal of Industrial Medicine, 1980-present. Member, WHO Programme Advisory Committee, 1980-present; Chairman, 1980-81. Editorial Board, Risk Analysis, 1981-present. Editorial Board, Regulatory Toxicology and Pharmacology, 1981-present. Arnold J. Lehman Award, Society of Toxicology, 1983. Member, US Delegation to the US-Japan Cooperative Medical Science Program Committee, 1984-present.

SUMMARY STATEMENT

Dr. RALL. Thank you very much, Mr. Chairman. It is a pleasure to briefly describe NIEHS, and particularly so this year since NIEHS will, in early December, celebrate its 20th birthday.

In looking back, it certainly has been a lively and busy 20 years. With the support of this committee, I think we have built a very solid record of achievement in what really is a new scientific field, environmental health. Our Institute has been able to provide stable support to the very best scientists working to define a new area of research, environmental health science.

We have also built a cadre of scientists who are able to address these problems. We are pleased that they are now increasingly moving into positions of importance in our fellow regulatory agencies. It seems to me that this is one of the important aspects of any institute, and that is to train new scientists.

We have uncovered a number of new health hazards, which worry a lot of people, but I think that it is also important to know that we demonstrated some significant nonhazards.

METHYLENE CHLORIDE

Among the most recent compounds that we have shown to be hazardous is methylene chloride, of which 500 million pounds a year is produced. Methylene chloride is a potent carcinogen, as well as having a variety of other toxic effects.

You may have read about how silly it is to worry about methylene chloride since it's used to decaffeinate coffee, and there is only a trivial amount in the decaffeinated coffee. That is absolutely true—nobody argues about that. But 25 percent of methylene chloride is used as a paint remover. If you take an old chest down into your basement and remove the paint with methylene chloride, you are breathing more methylene chloride than our rats and mice did when they were on tests.

It is also used as a degreasing agent. If you want to clean a carburetor or something like that, and do it where there isn't good ventilation, you can get heavily exposed to methylene chloride. Further, it is a propellant in many aerosol containers.

There has been an interesting sort of campaign to deemphasize the importance of methylene chloride based on the argument that you hardly get any in decaffeinated coffee. That is fine, but you can get heavy exposure to it removing paint, degreasing, and using propellants. So it is a very serious public health problem.

DIOXIN

Early in our Institute's history, we showed the enormous toxicity of dioxin, particularly its teratogenicity, and we have, for the last 20 years, supported the research on asbestos which has led, finally, to a good understanding of its hazards.

ASBESTOS IN DRINKING WATER

I should also remind you that we fairly often are able to say, don't worry about something. Asbestos in drinking water, for example. In Duluth, MN, about 15 years ago, there was great concern about taconite tailings, which contained very fine asbestos, and everybody in Duluth was drinking water heavily contaminated with asbestos.

After some very long and expensive studies, we are now able to say that asbestos as it is found in the current drinking water is not a hazard, and I think that that is terribly important.

PCB'S IN MOTHER'S MILK

There was great concern about the polychlorinated biphenyls in mother's milk. We mounted a large prospective study in North Carolina in which we followed about 1,000 kids, who are now 5 years old. Our findings indicate that there doesn't seem to be any major problem with PCB's in mother's milk but we are still working on it looking for subtle effects. That doesn't make the headlines, but I think that it is terribly important.

INADEQUATELY TESTED DRUGS

We have also begun to look at some drugs which had been widely used before the 1962 amendments, but which were never really adequately tested. Vitamin C, for instance, is perfectly safe. A very important group of antihistamines were found to be nonhazardous, but this doesn't make the headlines. I think it is a very important part of our task.

TOXICITY

Finally, we are beginning to define toxicity in a quantitative way, to attempt to answer the question of how bad is it, how toxic is it. It is very hard to answer for a population. We have talked about the six-city survey with air pollution, and some of the lead problems. This research is to try to define how toxic something is.

Finally, we created a large science base that I think will help us solve problems somewhat more easily in the future.

Thank you. Our request for this year is $188 million, and I would be pleased to answer any questions.

CLINICAL TRIALS

Senator WEICKER. Does your Institute conduct clinical trials?

Dr. RALL. No; we do, however, do testing. We have a program of testing chemicals, and in some ways that is like a clinical trial. It takes a long time to set up and go through, and we will be affected by the cuts in the testing program.

PCB'S

Senator WEICKER. It is never easy to put on public display one's ignorance, but I find I don't get as many opportunities as I do here to get great knowledge to put my questions to.

What are PCB's? I hear about this all the time, and I don't really know. What are they, and maybe just give me a little run down on that.

Dr. RALL. They are a family of closely related organic chemicals that are fluid at room temperature. They do not burn and they insulate against the transmission of electricity. These are characteristics that made them ideal to use in transformers, large transformers, as insulating materials and as materials that would help to conduct the heat from the transformer to the metal casings, so it would be dissipated.

Senator WEICKER. You say that they are liquid at room temperature.

Dr. RALL. That is right. They began to be made in the 1940's and 1950's, and in the late 1960's, a Swedish scientist discovered that there were high quantities of PCB's in birds in the Baltic Sea, but nobody had any idea where they came from.

In the late 1960's, early 1970's, we began to track back about 100 million pounds of PCB's and much of it ultimately went into the environment. On a smaller scale, the PCB's are still found in transformers and in fluorescent lights. They are mildly carcinogenic. They have some effect on growth and reproduction at higher doses in monkeys. They do things to your body enzymes that metabolize drugs. They stimulate michrosomal metabolism, so that many drugs are gotten rid of more quickly.

They are persistent both in the human body and in the environment, and that is the problem. The Toxic Substance Control Act back in 1976 declared them unacceptable, and ordered EPA to set up a series of regulations that would essentially rid PCB's from continued production and use over the next 5 or 10 year period.

That has happened now, and there are no more new PCB's on the market, but there is probably 1 billion pounds or so, or perhaps 2 billion pounds, in the environment. So the problem has decreased, but it is still there.

We publish a journal, the Environmental Health Prospectives, and the first issue of that journal in 1971 was devoted to a symposium on PCB's, which really laid out the problem very, very well. It is a problem, I think you can say, that has been looked at and solved in part by getting rid of the compound. In this instance, substitutes have been developed, but because of the large amount still sitting in the environment, we have to worry about it. That was probably a longer answer than it should have been.

Senator WEICKER. No; it was a very good answer.

Give me an example of an installation here in the eastern United States that probably still has PCB's.

Dr. RALL. The Smithsonian. The Washington Post has been full of the problems of the Smithsonian with its transformers inside the building, which are loaded with PCB's. The problem is that in a fire, they can blow up.

Senator WEICKER. In their present form, in the Smithsonian, they are enclosed and they are harmless?

Dr. RALL. Yes.

Senator WEICKER. But should an accident occur, then they get released into the environment.

Dr. RALL. In the State Office Building in Binghamton, NY, that happened, and a large transformer burst during a fire, and it spread PCB's throughout the entire building, and it was shut down for years.

The PCB's I am talking about contain contaminants which are very much like dioxin, and that, in fact, is probably the very toxic compound. It is a fascinating story.

RADON

Senator WEICKER. One of the local television stations recently ran a news series reporting on the dangers of radon gas in homes in the Washington area. Did you see the report, or are you familiar with the problem?

I believe Senator Specter raised this and got a response from you in the room the other day. Would you like now to give us sort of a more complete explanation of this situation?

Dr. RALL. I can't give a very much more complete view. NIEHS made a decision many years ago not to deal with radioactivity and radiation problems. From my general knowledge, it is, indeed, a very serious problem. Radon gas comes from deposits related to uranium that are in the ground. It is slowly released, it gets into basements, it permeates the whole house.

There is a geologic band through New Jersey and Pennsylvania that is quite heavily contaminated. This is all natural, this is from the Earth. There are other sporadic areas of radon contamination.

There is an article in the New York Times of yesterday suggesting that in the worst houses it may be equivalent to lower degrees of cigarette smoking.

I talked to Dick Adamson, who is a division director at the Cancer Institute, after Senator Specter asked that question. Dr. Adamson said they have three studies on radon gas in homes, and I think a summary is being made available to you. NCI is testifying at this moment on the House side, so I suspect that nobody is here from NCI, but you might want to ask them for more details later on.

Dr. WYNGAARDEN. I would be happy to have NCI put anything in the record that you would like.

INDOOR AIR POLLUTION

Senator WEICKER. OK, I would appreciate that.

Dr. RALL. It is a serious problem. There is an article in the Consumers Report of about 3 months ago that describes ventilators for homes that are designed to vent the radon out of the home where it can dissipate.

Indoor air pollution is a significant problem, particularly if you have a gas stove. In one of our six-city surveys, air pollution surveys, they also looked at air quality inside the house. Kids who are brought up in a home with a gas stove have slight but demonstrable pulmonary function decrements compared to kids who were brought up in a house without a gas stove.

Again, as we needed energy efficiency, we sealed up the houses very tightly, and that is causing problems.

Senator WEICKER. The radon emanates from natural deposits of uranium. I never knew that there was such a band of uranium in New Jersey and New York.

Dr. RALL. It is not worth mining. It is very, very diluted, unconcentrated.

Senator WEICKER. Isn't part of the same thing true also for oil burning, there are certain things that are released there.

Dr. RALL. Anything burning, gas or oil.

Senator WEICKER. Coal.

Dr. RALL. Coal causes a variety of serious problems. One, the high temperature reacts with the nitrogen in the air, and you get nitrogen oxides, and these are irritating and can eventually form acid precipitation.

There tends to be sulfur in both oil and coal, not in gas, and the sulfur then combines with oxygen in burning, and gives you sulfur oxide, which again can be irritating and can form the main component of acid rain.

Anytime you burn anything, you have a lot of problems. We have a large center grant at MIT where a very nice thing has happened, the flame engineers have gotten together with the toxicologists, and they are designing different ways of burning coal and burning oil, fluidized beds, and so forth, and trying to measure the effluent that goes out the stack to find out methods that will reduce the nitrogen oxides and the sulfur oxides. It is a very interesting area, and I think they are making some progress.

There is a good article that came out yesterday in the New York Times.

CHEMICALS AROUND US

Senator WEICKER. Are your efforts, insofar as environmental science, do they mainly deal with the air around us, or do you get into the matter of the water around us as much as the atmosphere?

Dr. RALL. Basically, we get into the matter of the chemicals around us, whether they are in air, water, in foods, in solvents that we use, whatever. We try to deal with the generic problems.

CHEMICALS IN ANIMAL FEED

Senator WEICKER. Are you involved with the problem that I have been reading about lately, this chemical fattening or slimming of the animals that we eat, et cetera. Is that something that you are involved in?

Dr. RALL. We have been very involved in it in that one of the earliest ways of putting a lot of weight on animals was to feed them DES, a synthetic estrogen. This is an interestingly toxic compound. It used to be prescribed to pregnant mothers in the mistaken belief that it would protect their unborn baby against miscarriage, and that was not true. What it did was to cause a low but significant incidence of a very unusual vaginal carcinoma in the daughters of the mothers who had taken DES.

We were not involved in that clinical observation, but what we did was to point out that there is a perfectly parallel mouse model. That is, if you feed the mother mouse DES, the daughter mouse gets the same sort of clinical condition that the human daughter did.

In addition, we noticed that the sons of the DES mother mice have significant reproductive problems. We announced that in a science article at the same time that the clinicians noted that the sons of DES mothers have reproductive problems. Typically, the estrogens used in animal feed are carried on to the consumer, and are not good.

We know now that it is probably better not to fatten beef, and our Congressman from North Dakota suggested that it was even more economical to sell them at 1,000 pounds than to fatten one up to 1,100 or 1,200 pounds.

Senator WEICKER. Is this ongoing, are you investigating all the new things that are being done to livestock, poultry, and all the rest of this?

Dr. RALL. We try to keep up with it.

ENVIRONMENTAL PROBLEMS

Senator WEICKER. What do you consider to be right now the most pressing environmental problem from your vantage point in the country?

Dr. RALL. I haven't had that question for a while, and that is interesting. I think that the most pressing problem relates to the old compounds that we have had around for a long time. I mentioned the Toxic Substance Control Act. After 1976, we had mechanisms in place to look at essentially all new compounds for some degree of toxicity. For better or for worse, any new chemical that goes into commerce, that is used as a food, that is used as a food additive, or a drug, is screened for toxicity. The old chemicals are not always subjected to careful testing, so that is one of the problems.

COMBINATION TOXICITY

The second problem that worries me very much, that at times seems almost intractable is that of combinations. Chemical A is fairly benign, chemical B is fairly benign, but you put them together and they may become very dangerous.

We have a large study at the Academy of Sciences right now to try to assist us in doing better studies on combinations of chemicals. We are looking at chemicals that are found in drinking water, and testing them in animals in the combination found in drinking water at much higher concentrations.

We have some interesting studies with dioxin and some of its relatives in terms of dioxin's ability to cause teratogenic events, namely, facial abnormalities. Hydrocortisone actually synergizes or increases the teratogenic effect of dioxin.

It is this combination toxicity that we worry about. It is intractable because there are so many different compounds. As soon as you start making up combinations, you get into such very large numbers that it becomes ridiculous to ever think about testing them.

So we are looking very, very diligently at ways to do a better job of testing. I think generically, those are the two biggest problems, the old untested compounds, and combination toxicity.

TESTING PROGRAM

Senator WEICKER. Are you satisfied that any sort of an active program is in existence to go after these old problems, besides asbestos, and we are all alerted to that one, and trying to get rid of it.

Dr. RALL. It is pretty much NIEHS that does that. We do most of the chronic toxicity testing now in the Government, and probably in the world. We will have to scale back our testing program this year and next year, cutting back the number of new tests by about 30 percent because there simply will not be the money.

Senator WEICKER. In this case, what you are talking about is personnel?

Dr. RALL. No; this is more dollars.

Senator WEICKER. The personnel to do the testing program, is that what it is?

Dr. RALL. Our testing program is largely done on a contract basis, and that means that it is not as personnel intensive as if we did it ourselves. But that means that it takes dollars, and we don't have the dollars that we did before.

QUALITY ASSURANCE

The cuts in personnel mean that we will not be able to do some of the quality assurance that we had planned on doing. These 2-year chronic toxicity tests are enormously complex, with thousands of animals, hundreds of data points. You have to follow these animals for 2 years, do the clinical chemistry on them, and then do the pathology.

Then you have to keep track of all of this so that you know this slide belongs to this animal that got this treatment.

We had, some years ago, a bad contractor who did not do a good job of this, and we have been very sensitive since then. After each experiment, we do a complete data audit which is to ensure that there is a trail of evidence, that all of this happened properly. That is labor intensive, and we do much of that ourselves. We are not going to be able to do as much of that in the future, and that worries me very much indeed.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Thank you very much. There will be further questions for response to the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

PCBs

Question. I read recently that the Environmental Protection Agency had given its permission for the burning of PCB-contaminated oil 140 miles off the coast of Maryland. What happens to PCB when it is burned--is the compound totally destroyed or does some small amount vaporize and remain in the atmosphere?

Answer. The regulations require destruction to 99.9999%. It is possible using current techniques to achieve that level and at that point PCBs can be considered to be essentially totally destroyed.

Question. Is burning the safest way to destroy PCB's, or is it the most economic?

Answer. It is our opinion that burning at proper temperatures is the safest method of disposal since it totally destroys the PCB. However, close monitoring of the equipment and technique is required for it to operate effectively.

NEW POLLUTANTS

Question. Our industrial society is constantly producing new technologies that could well be introducing new pollutants into our environment. Do you or any other Federal agencies have a mechanism in place that would allow monitoring new technologies for potentially dangerous environmental pollutants?

Answer. The Toxic Substances Control Act, which was passed in 1978, mandates that industry test certain new substances prior to introduction into commerce and EPA monitors the results of these tests.

The National Institute of Environmental Health Sciences has the ability to study the health effect of any possibly harmful chemical substances that may be introduced into the environment and works very closely with the Office of Toxic Substances of the Environmental Protection Agency, but this Institute has no regulatory activity.

TRAINING

Question. You indicate that you have been able to build a "Cadre of scientists with unique expertise to address environmental health problems". However, I notice that your FY 1987 budget proposes to reduce the number of new training positions by almost half (12 vs. 20). Given the fact that environmentally caused health problems are a constant factor of living in an industrial society, are we producing enough trained research scientists to tackle present and future problems?

Answer. The 1987 President's Budget proposes a reduction in the number of new individual awards of 6, from 18 to 12. The total number of trainees supported by NIEHS in 1987 is 442, compared to 475 in 1986 and 483 in 1985. From the 483 trained in 1985 NIEHS produced 198 new scientists in environmental toxicology, pathology, mutagenesis and epidemiology/biostatistics. About 132 of these were toxicologists. The 1987 request level will produce approximately 181 new scientists which is probably an adequate level.

Question. In your professional judgement, how many scientists should your institute be training each year?

Answer. Ideally, an additional four or five new institutional grants producing 15-20 new graduates each year and 8 new individual fellowships producing 4 new postdoctorates could be supported. This would increase our annual output of scientists by 10 to a level of about 191.

ACID RAIN

Question. In your opening statement you indicate that acid rain is a complex phenomenom that would require a study of the pollutants and metals found in rain. I think it is pretty clear that acid rain is a major environmental problem. What are your plans to increase the research effort in this area?

Answer. Additional research concerning health effects of acid rain should focus on three areas where new or additional studies are needed. The first involves more and better epidemiological studies that relate clinical effects of exposure to episodes of acid rain. Approaches to this problem may include the correlation of excesses in hospital admissions with indices of acid rain and levels of ambient sulfate and ozone.

A second need concerns better understanding between synergisms or antagonisms among toxic substances involved in the acid rain phenomenon. In terms of gaseous air pollutants, specific roles of components of acidic aerosols--hydrogen ion, sulfuric acid, ammonium sulfate, and other inorganic sulfate compounds--are receiving only limited study. An essential part of this need is development of a methodology that will discern each component within the ambient environment. Synergisms and antagonisms between potentially toxic metals and metabolism of essential metals are also of importance in the understanding of minimally toxic effects.

The third need concerns potential health effects of aluminum. Basic and clinical information is needed regarding effects of acidification of water on aluminum absorption, and deposition in mammalian system, and possible relationship of aluminum accumulation in body tissues to specific diseases, for example, diseases of kidney, bone, and nervous system.

Question. How much are you requesting in your FY 1987 budget for this type of research?

Answer. Approximately ten million dollars is included in the 1987 budget request for research on health effects of air pollutants which are relevant to the topic of acid rain and a similar amount on health effects of toxic metals, lead, cadmium, mercury, and other toxic metals in the environment. Although most of this research is toxicologic and addresses health effects of these metals, a large portion is germane to the health effects of the acid rain phenomenon.

Question. Given the seriousness of the problem, what, in your professional judgement, should we be spending on this research?

Answer. We estimate that $3,000,000 additional funding would be required to initiate studies in the three areas previously mentioned.

CENTERS

Question. During last year's hearing the subcommittee expressed concern over the reduction in the number of research centers supported by your institute. I believe you planned to support 12 centers -- three of which were marine centers. How many were supported in FY 1986?

Answer. We were able to start one new core center, at Johns Hopkins, and two new Marine Centers, at Mount Desert Island Biological Laboratory in Maine and Oregon State University in Corvallis, Oregon. This brings our total to 10 core and 5 marine centers.

Question. How many will be supported this year?

Answer. This year we will continue to support these 15 centers.

Question. Can you identify the kind of research these centers will be conducting?

Answer. The Centers program is an extremely effective means to stimulate inter-disciplinary research, drawing strengths from scientific areas throughout the university at which the Center is based. Some of the strengths and research thrusts at our Centers include molecular and epidemiological studies of carcinogens and mutagens, inhalation toxicology of air pollutants, toxicity of metals such as lead, mercury and cadmium, molecular/cellular toxicology, environmental epidemiology, neurobehavioral toxicology, genetic toxicology, chemical carcinogenesis, toxicity of by-products of fossil fuels, and the utilization of aquatic species as models for environmentally-induced human diseases.

FY 1987 BUDGET VS. ENVIRONMENTAL EMERGENCIES

Question. I understand that most of the environmental health research supported by your institute is conducted within a rational plan devised by you in consultation with your advisory council. I am concerned, however, that with an FY 1987 Budget proposal that is $9 million less than FY 1986 appropriated levels you may be forced to compromise your abilities to respond to environmental emergencies. Please describe the process of response to these types of emergencies and explain how you will be able to maintain this ability within a reduced budget.

Answer. The major environmental emergency that we responded to this past year was the study of methyl isocyanate (MIC), the chemical responsible for the Bhopal, India disaster. We were asked by the U.S. State Department and the World Health Organization to do a complete and indepth study of this chemical to find out what are the potential long-term health problems in the Bhopal survivors, and to develop a toxicologic data base on MIC because a minimal amount of data is available in the literature.

NIEHS was asked to do this since it has the unique ability to study a highly toxic chemical safely and to focus several areas of expertise -- toxicology, pathology, reproduction, immunology, genetics, pulmonary function/physiology--on the problem. These studies were conducted by our staff in addition to their normal workload and

involved significant in-house and contractor resources. If in the future an emergency such as this were to occur that would require resources in excess of what NIEHS could provide, additional funding would be necessary.

ONCOGENES

Question. You mention in your opening statement that scientists supported by your Institute are doing research on cancer causing oncogenes. How are you coordinating this research with the Cancer Institute to avoid unnecessary duplication?

Answer. Our research on cancer causing oncogenes is a collaborative effort with the Cancer Institute. This collaborative effort takes advantage of the large number of tumors collected and stored by NIEHS as part of the NIEHS National Toxicology Program (NTP) testing program. The results of this collaboration have already borne fruit in that new oncogenes have been discovered which may help to identify the relationship between specific oncogenes and selective types of tumors.

BUDGET REDUCTION VS. RESEARCH PROGRAMS

Question. During last year's hearings you responded to a question in the record concerning the impact of a reduction in funding in FY 1985 on your intramural research program as follows: "We will try to assure this administrative reduction will have minimal impact on the research programs." FY 1985 is now history. Specifically what was the impact of the loss of $359,000 on the intramural research program?

Answer. The reduction in funding was related to two items; a proposed rescission of $226,000, and a withholding for consultant services of $133,000 as required by Section 515 of the Treasury Postal Services Appropriation Act of 1985. The proposed rescission was not accepted by Congress. Funds were withheld from obligation which resulted in less use of consultant services. Therefore, no real negative impact was felt in the intramural research program.

IMPACT OF BUDGET REDUCTION

Question. The President's Budget proposal for FY 1987 reduces your budget by $9,483,000 under FY 1986 appropriated levels. Gramm-Rudman-Hollings; if triggered, could reduce your budget even further--maybe by as much as 20 percent. I know this would reduce the number of grants, possibly the size of grants, centers, training, etc. but can you give us some idea of the impact of these reductions on the kinds of research that would be stopped or lost?

Answer. If NIEHS had to absorb a budget reduction of about twenty percent in 1987, all programs and mechanisms of funding would be affected. Certainly, no new initiatives would be started. Across the board cuts resulting in less of everything would probably not be feasible; rather, individual programs or projects would have to be assessed and prioritized.

Question. What impact might this have on the health of our citizens five and ten years down the road?

Answer. I cannot adequately judge the effect reduced funding would have on research results and ultimately national health. As you know, biomedical research is usually a methodical, time-consuming process although breakthroughs can occur spontaneously--sometimes by accident. Interruptions in this process could be harmful. I think your question must have input from the entire biomedical research community before a really meaningful answer can be given.

Question. Can you discuss your contingency plans if these massive budget cuts should come to pass?

Answer. Since the 1987 President's Budget was developed within the provisions of Gramm-Rudman-Hollings, no contingency plan for further sequestration has been developed by NIEHS or NIH.

AUTOMATIC PROVISIONS OF GRAMM-RUDMAN-HOLLINGS

Question. If the automatic provisions of Gramm-Rudman-Hollings are triggered in FY 1987, your institute may well have its budget reduced by 20-25%. Have you prepared a contingency plan in the event Gramm-Rudman-Hollings becomes reality?

Answer. A contingency plan has not been developed because the 1987 request was developed within the provisions of Gramm-Rudman-Hollings.

Question. If cuts of this magnitude become reality, how will they be distributed: intramural versus extramural programs; peer review system--would number of site visits be reduced, would travel to NIEHS study section meetings be affected: would NIEHS employees have to be furloughed; and what major programs would have to be cut back?

Answer. If further cuts of this magnitude were to become reality for NIEHS in 1987, all programs would be affected. Difficult decisions would have to be made as to whether or not to continue some projects. Expenses such as travel, supplies and equipment would be significantly reduced. Possible furloughing of staff could result but only as a last resort.

Question. Please list the research programs of the highest priority that should not be cut and why.

Answer. I could answer this question from the perspective of NIEHS, but I think the answer must involve more than the individual programs of the individual institutes. It is at least NIH-wide and, most probably, DHHS-wide. In other words, when the time comes that individual programs must be ranked in order of funding then a concensus of everyone involved should be sought.

RADON GAS IN D.C. HOMES

Question. One of Washington's TV stations recently ran a news series reporting on the dangers of radon gas in homes in the Washington area. Did you see this report, or are you familiar with this problem and what can you tell us about this problem?

Answer. Radon and its alpha-emitting decay products contribute a significant portion of the dose of background radiation that people are exposed to from natural sources. The major issue in the "radon problem" is that radon gas is emitted from soil in varying amounts, depending on the geology of the location. In some localities, the amount entering a home from soil under the house is often an order of magnitude greater than outdoor concentrations and is made worse by decreasing air exchange within a house. The National Cancer Institute has the responsibility for studies of radon gas.

Question. How dangerous to health is Radon Gas?

Answer. The principal health effect of radiation is cancer, but the dose response relationships for alpha-emitting radionuclides are not sufficiently certain to allow quantitation of the health risk associated with measured indoor concentrations. Also, techniques are available to ventilate houses to reduce radon gas levels.

Question. Do you have or are you planning to conduct any studies on the effect of high concentrations of radon gas in the home--are you requesting sufficient funding to explore this problem and, if not, how much will you need or can you offer any suggestions to the residents of the D.C. area?

Answer. The National Cancer Institute has responsibility for research on radon gas and therefore we have no plans to conduct studies on its effects. However, we will of course assist NCI if we can be of any help.

Questions Submitted by Senator William Proxmire

ALUMINUM

Question. Dr. Rall, on the last page of your prepared statement you mention research into the potential health effects of aluminum as a new initiative. How much do you plan to spend on such research next year?

Answer. We plan to support five or six new research grants in response to a request for applications for a total of about one million dollars.

Question. Can you tell us why this should be a new initiative?

Answer. New research initiatives regarding the potential human health effects of aluminum are needed because the amount and the chemical form of aluminum dissolved in water is increased by acid rain making it more available for absorption and distribution in body tissues.

Aluminum is abundant in the environment and there is increasing evidence that it is associated with certain diseases, particularly of the central nervous system. An encephalopathy occurs in hemodialysis patients that is related to aluminum content in water and, finally, aluminum is present in neural tangles in the central nervous system of persons with Alzheimer's disease. There are gaps in the understanding of the role of aluminum speciation and transport in human tissues, particularly across the blood-brain barrier, as

well as the cellular pathology of aluminum. In particular, there are few, if any, appropriate animal models to date. Now research initiatives are needed to address these issues.

1,3 BUTADIENE

Question. Last year in a response submitted for the hearing record you indicated that you had done a substantial amount of testing of butadiene and planned to do further studies to develop dose response carcinogenicity data in mice as well as differences in sensitivity in different species of rodents. Where do you stand in your butadiene research and has your work resulted in a change in the workplace standard for this chemical?

Answer. An extensive research program on the toxicity and carcinogenicity of butadiene in rats and mice has been developed and is currently in progress. In our earlier study, high rates of multiple types of tumors were observed in male and female mice. That study, which was intended to last for 103 weeks, was ended after 60 weeks because of reduced survival due to malignant tumors--mainly lymphomas and hemangiosarcomas of the heart. The exposure levels used in that study were equal to or below the OSHA standard.

A new 2-year inhalation study was begun in January 1986 to better characterize dose response relationships for butadiene induced neoplastic and nonneoplastic lesions in mice. The data from this study will not be available until 1989.

A subchronic study in rats is also in progress to determine the toxic effects and dose response relationships of butadiene in this specie. Although the data have not been fully evaluated, preliminary findings indicate that there were marked chromosomal effects.

Because of the difference in the tumor response of butadiene in rats and mice, pharmacokinetic studies were initiated nearly 2 years ago to compare the absorption, metabolism, distribution, and/or excretion. A greater rate of metabolism of butadiene was observed in mice than in rats; this factor may contribute to the greater sensitivity of mice to butadiene than rats. In addition, teratology studies--rats and mice--are underway.

Based on the results of the NTP carcinogenicity study of butadiene in mice, the International Agency for Research on Cancer concluded that there was sufficient evidence for the carcinogenicity of butadiene in experimental animals. The American Conference of Governmental Industrial Hygienists now recommends a threshold limit value of 10 ppm for butadiene. The EPA concluded that the manufacture and processing of butadiene present an unreasonable risk of cancer to exposed workers. On October 10, 1985, the EPA, acting under section 9(a) of the Toxic Substances Control Act, referred butadiene to OSHA for consideration and possible regulatory action.

REGULATORY ACTIONS

Question. Outline briefly any federal or private regulatory actions that have been taken over the last year or so to implement the results of your toxicity studies.

Answer. Once reports for long term toxicological and carcinogenesis studies are peer reviewed by the NTP Board of Scientific Counselors, they are made available to the various agencies. Exact usage of all the data results by regulatory agencies is not known. However, we do know of several instances in which the data were

utilized. For example, the positive results from the NTP carcinogenesis study of 1,3-butadiene in mice were utilized by EPA in deciding to initiate a 180-day review of the chemical under Section 4(f) of the Toxic Substances Control Act. In October, 1985 the EPA acting under Section 9(a) of the Toxic Substances Control Act referred 1,3-Butadiene to OSHA for consideration and possible regulatory action. OSHA has published a notice in the Federal Register requesting interested parties to submit data and comments relevant to determining the risk of potential adverse health effects of 1,3-butadiene. As another example, the positive results from the NTP inhalation carcinogenesis studies of Methylene Chloride in mice and rats were utilized by EPA in deciding to initiate a priority review of the chemical under section 4(f) of the Toxic Substances Control Act for risks of human cancer from certain exposure to Methylene Chloride. Subsequently, the EPA announced in the Federal Register its intention to conduct, in consultation with other Federal agencies, a comprehensive and integrated regulatory investigation of the chemical. Recently, the FDA published in the Federal Register a rule to ban the use of Methylene Chloride as an ingredient in cosmetic products based on the results from NTP studies. Finally, the Consumer Product Safety Commission is considering a number of actions for decreasing exposure to Methylene Chloride in paint strippers and spray paints. Among the options is a possible mandatory labeling standard for such products. Further, EPA made use of the positive results from two NTP/NCI carcinogenesis studies of Ethylene Dibromide in its decision to eliminate certain uses of this chemical as a pesticide.

I have been impressed that many industries that produce chemicals institute their own rules to limit exposure to substances we show are potentially hazardous well in advance of any federal regulatory process.

JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES

STATEMENT OF DR. CRAIG K. WALLACE, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

DR. CORALIE FARLEE, ASSISTANT DIRECTOR FOR PLANNING AND EVALUATION, JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES

PREPARED STATEMENT

Senator WEICKER. Next we will hear from Dr. Craig Wallace, Director of the John E. Fogarty International Center. The Fogarty Center provides the opportunity for an international exchange of scientists and scientific information. It also provides funding to the Gorgas Memorial Institute for research in tropical diseases.

Dr. Wallace, it is a pleasure to have you here. Your statement in its entirety will be included in the record, please proceed.

[The statement follows:]

Statement of Dr. Craig K. Wallace

"We live in an era when the attention of the world is focused on the efforts of nations to find ways to work together in common purpose." These were the words with which Congressman John E. Fogarty opened his address to the World Health Assembly in 1962. They are no less appropriate today.

As Congressman Fogarty so aptly indicated, to attain the highest level of health worldwide, international medical research must be promoted in the interests of scientific advances. We must support medical research performed by foreign scientists whenever such studies will advance both the health status of the United States and the country in which the research is conducted. We must avail ourselves of the unequaled and often superior opportunities for our own research agendas. By uniting different approaches, greater progress can be made in a shorter amount of time--all mankind can benefit.

As we move into an era of constrained resources, we are giving careful attention to priorities and the effective use of those resources. We must assure that we do not retreat from our international perspective, involvement, and leadership. It is as important as ever, if not more so, that U.S. and foreign scientists continue to have opportunities to meet, discuss, and analyze their respective work, that U.S. and foreign scientists continue to have opportunities to collaborate in laboratories and share their unique talents toward common research objectives. U.S. and foreign scientists must continue to examine together those major health research issues that evolve and emerge as common, worldwide concerns.

As the focus for NIH international activities, the Fogarty International Center is unique in its responsibility to further international biomedical collaboration. It does this at every level--between scientists, between institutions, and between governments. Through its various programs that broaden international cooperation and agreement, the Fogarty International Center functions to maintain U.S. leadership in biomedical research while taking advantage of opportunities offered throughout the world that will enhance the health of the American people.

Under its Advanced Studies Programs, the Fogarty International Center is continuing its activities dealing with those infectious diseases considered candidates for foreseeable eradication. For example, there are in the world an estimated 1 million persons infected with yaws, a disease previously thought to be virtually conquered. In certain regions, particularly West and Central Africa, the situation is precarious; the proportion of children with infectious yaws is approaching that of pre-penicillin years. In 1985, as a followup to its 1984 international symposium on yaws and other endemic treponematoses, the Fogarty International Center initiated a meeting, in cooperation with the WHO and held in Indonesia, of Asian countries to stimulate and strengthen primary health care services by coupling curative treatment with prevention (immunization). Future activities include a 1986 meeting on yaws to determine the present epidemiological situation in the African region and to consider integrated control measures and the cost of implementing yaws treatment in children as part of the primary health care services in each country. The Fogarty International Center, together with a number of international organizations, is working to transfer state-of-the-art research results in the form of newly developed diagnostic techniques. We are also taking advantage of the research opportunities in this initiative to study

penicillin resistance to the treponematoses--the agent causing yaws. Such research is important because of penicillin resistance in the closely related organisms that cause syphilis. It is further important to obtain this information to avert a potentially greater problem worldwide.

Another research effort in this program stems from the 1982 international symposium on poliomyelitis sponsored by the Fogarty International Center. Dr. Albert Sabin, senior expert consultant at the Fogarty International Center, is coordinating eradication activities for this infectious disease. He is also collaborating with colleagues to evaluate the aerosol vaccine and other approaches to measles vaccination, a direct outcome of the Fogarty International Center 1982 symposium on measles. These efforts with measles are particularly important to the United States: if susceptible non-immunized individuals either in this country or abroad are exposed to these viruses, the risk is great for individual infection or even outbreaks of an epidemic in a susceptible community.

The Fogarty International Center International Research and Awards Programs sponsor foreign scientists to work in U.S. laboratories and send U.S. researchers to foreign scientific institutions to conduct research of mutual interest, covering a wide range of scientific approaches. Their research is concentrated in areas of current global health concern--most generally neoplastic, metabolic, and infectious diseases. Such programs not only contribute to the development of scientists and their countries' resources but, more importantly, ensure the continuation of American influence and leadership in biomedical science.

In its role as the operational link between the NIH and other U.S. agencies and international organizations concerned with problems of world health, the Fogarty International Center facilitates the NIH's collaborative relationships in biomedical research with over 70 countries. Among these countries, China and India are of priority interest to the U.S. Government for maintaining strong cooperation in science and technology. With both countries, the NIH has major linkages of mutual benefit developed through the efforts of the Fogarty International Center. One of the several activities with China that we facilitated is the development of an understanding with the Chinese Academy of Medical Sciences to implement a health scientist exchange program that is intended to foster contacts between scientists in areas outside those under the existing agreements. We are also facilitating the implementation of collaborative activities under a separate agreement between the NIH and the Chinese Academy of Sciences, involving NCI, NIADDK, and counterpart institutions.

In the instance of India, the Fogarty International Center is coordinating NIH requirements for funding under the new U.S.-India Fund for Cultural, Educational, and Scientific Cooperation. This fund will support projects being proposed by NIAID, NHLBI, DRS, NIDR, and NLM and is replacing the former P.L.-480 Program for India. Thus U.S.-owned rupees will generate interest that can be used for U.S. projects. It is expected that about $1.2 million will be available annually for PHS health-related projects.

The Fogarty International Center plays a key role in the technical management of a new major program with India, the Vaccine Action Program, which was announced by President Reagan and Prime Minister Gandhi following the Prime Minister's state visit in June 1985. This new program follows other successful collaborations in science and technology but differs in that it is focused on diseases that can be prevented through immunization programs rather

than on a particular component of technology. It is comprehensive, covering a broad range of activities from basic research and development of new and improved vaccines to strengthening the quality control and vaccine manufacturing capability in the Indian private sector. The Vaccine Action Program incorporates interest both in science and technology collaboration and in immunization programs, the latter a critical feature of child survival programs throughout the world. In addition, the Vaccine Action Program will provide an opportunity for U.S. scientists who are working on vaccine development to pursue their studies through field study phase, an opportunity all too frequently unavailable.

In its role as the WHO Collaborating Center for Research and Training in Biomedicine, the Fogarty International Center sponsored --in cooperation with Gorgas Memorial Laboratory, the Pan American Health Organization, and others--a workshop on training needs in entomology for vector-borne disease research and control, held in Panama in October 1985. This project should be a significant factor in furthering regional and global strategies in manpower development for control of major vector-borne diseases. Further, in cooperation with the PAHO and the WHO, we are currently conducting a project in the Region of the Americas to identify patterns of international research collaboration between developed and developing countries as well as among developing countries. As a result of this project, we will be able to recommend strategies for strengthening health research capabilities of scientists to participate in the research mission of the NIH.

The Gorgas Memorial Institute and its Laboratory in Panama receive core support through the Fogarty International Center appropriation. The Fogarty International Center has supported site visits to the Laboratory to encourage the strengthening of their research and is urging the Institute to develop additional sources of funding so that the Laboratory may continue to be an important resource for the United States.

The various program activities of the Fogarty International Center are but threads of a tightly woven cloth encompassing much of the world by which NIH objectives are enhanced and shared. How else but with China and other countries will we learn about the variegated patterns and factors that influence the development of cancer? How else but with India and other countries will we be able to have a broad enough base to perfect new and better vaccines against infectious diseases? How else but with African and other countries can we trace the evolution of AIDS and its various manifestations? How else shall we be aware of research advances taking place in the Soviet Union and other Eastern European countries if it were not for our cooperative exchange agreements?

These activities were the reasons for the establishment of the Fogarty International Center in 1968 and its recent reconfirmation in legislation. These activities have been and will continue to be priorities of the Fogarty International Center. They are necessary and important to U.S. biomedical research interests and cannot be conducted without the Fogarty International Center.

In conclusion, I quote Congressman Fogarty: "Just as disease knows no boundaries, so also the benefits of medical research and indeed research itself can know no boundaries." To support the Fogarty International Center, we request $11,305,000 for FY 1987.

Biography of Dr. Craig K. Wallace

December 4, 1928. Woodbury, N.J. Married, two children.

Education. A.B. (cum laude), Princeton University, 1950. University of Virginia, School of Law, 1951. M.D., New York Medical College, 1955.

Professional History. 1955-1960, Intern, Medical Resident, and Chief Resident, Jefferson Medical College Hospital, Philadelphia, Pa. 1960-1963, Clinical Investigator, Naval Medical Research Unit (NAMRU) No. 2, Taipei, Taiwan. 1964-1969, Assistant Professor of Medicine, The Johns Hopkins University School of Medicine. 1964-1970, Assistant Professor of Pathobiology, The Johns Hopkins University School of Hygiene and Public Health. 1964-1966, Resident Coordinator and Head, Medical Program, The Johns Hopkins University Center for Medical Research and Training (CMRT), Calcutta, India. 1966-1969, Assistant Physician, The Johns Hopkins Hospital. 1967-1972, Associate Director, The Johns Hopkins University CMRT. 1969-1972, Associate Professor of Medicine, The Johns Hopkins University School of Medicine. 1969-1972, Physician, The Johns Hopkins Hospital. 1971-1972, Associate Professor of Pathobiology, The Johns Hopkins University School of Hygiene and Public Health. 1972-1974, Head, Research Detachment, NAMRU-3, Addis Ababa, Ethiopia. 1974-1976, Commanding Officer, NAMRU-5, Addis Ababa, Ethiopia. 1976-1978, Program Manager, Infectious Diseases Research, Naval Medical Research and Development Command, Bethesda, Md. 1978-1981, Chief of Internal Medicine, Naval Regional Medical Center, Camp Pendleton, Calif. 1981-1982, Director of Clinical Services, Naval Regional Medical Center, Jacksonville, Fla. 1982-1984, Commanding Officer, NAMRU-3, Cairo, Egypt.

Professional Associations. Fellow of the American College of Physicians; Fellow of Infectious Diseases Society of America; Fellow of the Royal Society of Medicine; Fellow of the Royal Society of Tropical Medicine and Hygiene; American Association for World Health; American Medical Association; American Society for Microbiology; American Society of Tropical Medicine and Hygiene; Association of Military Surgeons of the United States; The National Foundation for Infectious Diseases; National Council for International Health; The Professional Association of the Commissioned Corps of the U.S. Public Health Service.

Honors, Awards. Armed Forces Reserve Medal, 1975. Meritorious Service Medal, with Gold Star in lieu of the Second Award, 1976, 1984. Navy Commendation Medal, 1982.

INTRODUCTION OF ASSOCIATE

Dr. WALLACE. Thank you very much, Mr. Chairman. It is nice to be here.

I would like to introduce Dr. Coralie Farlee, the Assistant Director for Planning and Evaluation for the Fogarty International Center.

I would like to underline a few points from my statement. I think at this particular time of budgetary restraint, it is very important that we do not retreat from our international perspective, our international involvement, and our international leadership in biomedical research. At the National Institutes of Health, as you know, the Fogarty International Center has a unique role; we act as the catalyst to encourage international collaboration at every level—government to government, institution to institution, and scientist to scientist.

We do not think in terms of international programs and domestic programs: Almost all of our biomedical research has an international component.

We fulfill our responsibilities in several ways. Through our advanced studies programs, we look at various research areas, which the other institutes are not addressing, are not ideally equipped to address or cross several institute areas—such things as preventable disabilities. Also, we are coordinating the 1987 International AIDS Conference on behalf of the Public Health Service.

Through our Research and Awards Program areas foreign scientists conduct collaborative research in laboratories throughout the United States, and Americans conduct research abroad. A number of purposes are served. It not only helps the development of foreign laboratories and foreign scientists, but it also allows Americans to take advantage of unique opportunities abroad that they wouldn't otherwise have.

These opportunities also help assure continued American leadership and influence in the biomedical research arena internationally.

Finally, at the NIH, we are the focus for the operational linkage between the NIH and other international and domestic agencies. In this area, we have agreements or other activities with some 70 countries. For example, in China, a country considered to be a priority by the administration, the Fogarty International Center has been responsible for establishing health scientist exchange through both the Chinese Academy of Medical Sciences and the Chinese Academy of Sciences.

In India, another country considered to be a priority by the administration, the FIC has technical management responsibility within the NIH for the Vaccine Action Program, involving a consortium of both United States and Indian agencies that is reviewing all areas of vaccine research development, and administration in India, and will be coordinating these activities.

For such activities as these, we are requesting $11,305,000 so that we do not retreat from our position of international leadership in biomedical research.

I will be happy to answer any questions.

Senator WEICKER. Where does that $11 million fit? What was the amount in fiscal year 1986, after the 4.3-percent cut?

Dr. WALLACE. After the 4.3 percent, in 1986, it was $10,893,000.

Senator WEICKER. Is there anything that I should know of the Gorgas Memorial Laboratory's efforts vis-a-vis tropical diseases, anything significant coming from that area?

Dr. WALLACE. The Gorgas Memorial Laboratory has continued to address vigorously their financial picture at the present time, and one-third of their budget does come from outside resources. Because of the cut in funds, they have had to curtail certain programs, they are not entertaining new initiatives, and they have reduced their program in acute respiratory diseases.

Senator WEICKER. How much do they get?

Dr. WALLACE. They get $1,913,000 this year.

Senator WEICKER. What is Gorgas going to do that the various institutes at the National Institutes of Health are not doing?

Dr. WALLACE. I think, No. 1, because of the location of the Gorgas Memorial Laboratory, in Central America, they are in a better position to address regional problems. Indeed, other institutes of the National Institutes of Health fund some of the research at the Gorgas Memorial Laboratory and supplement the core support. This includes cancer research, AIDS research, and malaria vaccine testing. The Gorgas Memorial Laboratory has a unique colony of aotus monkeys, which the Army is using to test malaria drugs.

Actually, the opportunities for Gorgas are tremendous. But they do not have the personnel to take advantage of them.

Senator WEICKER. With $1.9 million.

Dr. WALLACE. That is the core support.

Senator WEICKER. Are you saying that a good portion of their funding comes from private sources now?

Dr. WALLACE. One-third comes from sources other than the core support provided through the FIC appropriation. The laboratory is having a great deal of difficulty. Infectious diseases research is not as popular now as research in some other areas. The Institute has a new president who is primarily responsible for addressing fundraising, and they are making a decided effort to do that.

The laboratory has also cut down on its expenses in a number of areas. It needs capital improvement. The laboratory is extremely antiquated, and the buildings are in miserable shape. The library is literally sinking. These things have all had to be put on the back burner.

We, at the Fogarty International Center and the NIH, have tried to help them from a scientific point of view. We funded two site visits down there. Our emphasis and our efforts have been very much in trying to shore up the scientific endeavors.

Senator WEICKER. Are you sure that we are not continuing our funding of Gorgas with a rationale, well, it is there, and it has always been there?

Dr. WALLACE. I wouldn't say that the rationale for funding Gorgas has changed substantially over the years.

Senator WEICKER. When was Gorgas founded?

Dr. WALLACE. In 1928.

Senator WEICKER. Certainly, I think we would both agree that the National Institutes of Health have become something far different, in other words, since the 1920's, both in scope and the nature of the various institutes. It is an entirely different operation.

Dr. WALLACE. Yes; very much so.

Senator WEICKER. I have to question the fact as to whether or not the work that is done in Gorgas cannot be better accomplished in other ways, in other places, under your aegis, if you will, working with NIH.

I don't understand, if you tell me that the physical condition of the plant is as you have described it, if you had to make a decision today, would you go ahead and invest in a new physical plant in that spot, doing the things that they do?

Dr. WALLACE. If I were in a position with the funding, and what-not, that would not be my first priority, but I am not the director of the Gorgas.

Senator WEICKER. Right.

I think you have answered my question. I have just one more question, and there are others to be responded to for the record.

Can you describe the results of the recent Romanian cancer scientists to the NIH? What aspects of Romanian cancer research are of particular significance to NIH and the National Cancer Institute?

Dr. WALLACE. Mr. Chairman, I will have to submit that for the record, I do not recall offhand. We have a number of international visitors and exchange scientists.

Senator WEICKER. All right. Thank you very much.

[The information follows:]

ROMANIAN CANCER SCIENTISTS

Under a memorandum of agreement between the National Cancer Institute [NCI] and the Victor Babes Institute of Romania, the NCI supports visits to the United States by Romanian scientists for consultation and collaboration in cancer research. Under this agreement, Romanian scientists visit NIH laboratories and/or private sector institutions engaged in cancer research. The most recent visits, in late 1985, were made by Dr. Ioan Moraru and Dr. Andre Sulica of the Victor Babes Institute, Bucharest.

Dr. Moraru consulted with scientific counterparts at the Armed Forces Institute of Pathology, NCI, and three nongovernment institutions on new trends in histotyping of soft tissue tumors and the use of monoclonal antibodies in tumor diagnosis. Dr. Sulica discussed with immunologists at NCI recent research advances on the role of natural killer cells in modifying tumor growth.

These discussions resulted in the identification of subjects of mutual interest for possible inclusion in the agenda of the second joint meeting under the United States-Romania Cancer Program to be held in late 1986.

Aspects of Romanian cancer research are of particular significance to NIH and the National Cancer Institute. In addition to possible collaboration on histotyping, monoclonal antibodies in tumor diagnosis, and effects of killer cells on tumor growth, NCI and the Babes Institute share interests in studies of metabolic pathways that lead to activation and detoxification of carcinogens (such as polycyclic aromatic hydrocarbons).

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. There will be some other questions which we would like you to respond to for the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

MEDICAL COOPERATION

Question. After the Reagan-Gorbachev Summit meeting in November, the United States indicated that there would be an emphasis in the area of medical cooperation. What is being done to respond to this type of initiative?

Answer. The Fogarty International Center is responding to the initiative by exploring interest within the NIH in developing new areas of collaboration with the USSR. Examples are: the expansion of joint research on cardiovascular and cardiopulmonary diseases; expansion of the exchange of biomedical information between the National Library of Medicine and the USSR Ministry of Health to new areas such as space medicine, neurosciences, and cancer; and development of cooperation between U.S. and Soviet primate research centers (especially the world's largest and oldest center in Sukhumi, USSR) on viral oncology and immunology with specific reference to acquired immunodeficiency disease.

The FIC has proposed to triple the exchange quota under the US-USSR Health Scientist Exchange Program and has been able to allocate specific funds under the FY 1987 request to support this increase. Furthermore, the FIC is coordinating with the State Department plans for a visit to the USSR by the NIH Director. The purpose of the visit will be to discuss prospects for expanded cooperation and to negotiate the increased quota of exchanges under the Health Scientist Exchange Program.

Question. Will the level of funding requested in your FY 1987 budget allow the Fogarty Institute to respond fully to these opportunities?

Answer. We will be able to respond to those initiatives having greatest importance in this area.

GORGAS MEMORIAL INSTITUTE

Question. The Fogarty International Center provides about $1.9 million in core support for the Gorgas Memorial Institute (GMI) in Panama. How many dollars does the GMI receive in research grant dollars, and how many of these dollars come from other NIH institutes?

Answer. The GMI expects to receive approximately $571,000 in NIH research grant funds in 1986.

Question. Does the Gorgas Memorial Laboratory have research grants from any other sources? Can you give us some examples?

Answer. In addition to NIH grant support, the Gorgas Memorial Institute expects to receive additional funds and contributions from the Department of Defense, Yale University, the World Health and Pan American Health Organizations, and Panama totalling $441,000.

Question. What are some of the recent research advances in tropical medicine supported by the Gorgas Memorial Institute?

Answer. Gorgas Memorial Laboratory scientists demonstrated, as a result of intensive field surveillance efforts, that yellow fever virus is likely to cause an epizootic infection in the monkey population of eastern Panama in the near future and pose a threat to human populations. As a result of these findings, the Ministry of Health has intensified its yellow fever immunization program. In addition, Gorgas staff completed a comparative study of the effectiveness of two drugs, Glucantime and Pentostam, in the treatment of cutaneous leishmaniasis. They also demonstrated that two distinct transmission and clinical patterns of Chagas' disease occur in Panama, possibly due to concomitant infections with Trypanosoma cruzi and Trypanosoma rangeli.

Researchers adapted Plasmodium falciparum, the parasite causing the most virulent form of malaria, to the Aotus monkey, enabling the use of a primate model for evaluating candidate drugs for treating chloroquine-resistant malaria. Finally, Gorgas researchers developed an improved method for the isolation and early identification of St. Louis encephalitis virus, a major cause of epidemic encephalitis in the United States and of sporadic encephalitis cases in the tropical Americas.

Question. What new research initiatives in tropical medicine are being undertaken by the laboratory?

Answer. The Gorgas Memorial Laboratory (GML) has redirected its research program to include activities that will not only contribute to the prevention and control of the classical tropical diseases but will also address new medical problems in the tropics, such as the prevention and control of chronic diseases and acute respiratory infections. This approach reflects the position of the U.S. and other Member Nations of the World Health Organization in support of World Health Assembly resolutions to control the growing occurrence of chronic diseases in tropical countries. The GML is also endeavoring to take advantage of its geographic position in the isthmus to address major health problems in the tropics which transcend national boundaries and to serve as a regional site for research training and collaboration on health problems in the tropics. Examples of specific projects are the establishment of a collaborative multinational research program on the epidemiology of cervical cancer in Latin America; a long-term seroepidemiologic study of human T-cell lymphotropic virus type 1 (HTLV-I), the first human retrovirus shown to cause cancer, in Panama; a screening program for detecting sexually-transmitted diseases (including AIDS) in high-risk Panamanian populations; and epidemiological studies of acute respiratory disease in Panamanian children.

Question. Has the recently published report on tropical medicine research impacted on the long-range plans of the Gorgas Memorial Institute (GMI), and for that matter, on NIH in general?

Answer. The long-range plans of the GMI have been influenced by recommendations made in the Office of Technology Assessment (OTA) report on the Quality and Relevance of Research and Related Activities at the GML.

The OTA recommended specific changes which were based on information derived from in-depth interviews with the U.S. and Panamanian scientific community. First, the GMI should undertake more aggressive fund-raising in order to attract top university scientists for purposes of research collaboration and research training of young scientists from the U.S. and Latin American countries. Second, cooperative agreements and other mechanisms to support U.S. scientists' involvement should be pursued. Third, changes should be made in the structures of GMI and GML to improve program management. Fourth, long-range planning and an improved peer review process should be implemented to assure continued quality and relevance of the research program.

GML has responded toward implementing these recommendations. To address the issue of fund-raising, GMI has hired a new President who by mid-FY 1986 expects to have developed a fund-raising campaign to meet long-term planning objectives. New contacts for fund-raising have already been established with both the public and private sectors. To strengthen ties with the private sector, two vacancies on the Board of Directors were recently filled by members from U.S. industry. To address recommendations regarding collaboration with U.S. and Latin American scientists and institutions, GMI has attempted to intensify collaboration with the U.S. Navy and several U.S.-based universities. A cooperative agreement was signed in FY 1984 between the GMI and the University of Alabama School of Medicine, Department of Internal Medicine, for the purposes of research collaboration and research training. GML cancer research, supported in part by the NCI/NIH, is being undertaken through collaboration with the National Oncology Institute and the Ministry of Health in Panama; McMaster University, Canada; and National Cancer Units in Costa Rica and Colombia. Arbovirology, a long-standing research area at GML, is being strengthened through collaboration with the Yale Arbovirus Research Unit.

To strengthen relationships between the GMI and the GML, regularly scheduled visits by the President to the GML are designed to improve research management coordination. The Advisory Scientific Board and the Board of Directors of the GMI were asked to become involved in program development. Finally, since publication of the OTA report, two site visits sponsored by the FIC have addressed the matters of program quality and relevance.

A second OTA report, entitled "Status of Biomedical Research and Related Technology for Tropical Diseases" and published in 1985, goes beyond activities of the GML and addresses the overall status of U.S. funding for tropical disease research. Since the report was issued only about five months ago, it is too early to consider its impact on the NIH as a whole. However, two of seven options presented to Congress to encourage tropical disease research and development could have a direct effect on the National Institute of Allergy and Infectious Diseases (NIAID). These are: (1) increases in Congressional appropriations for tropical disease research; and (2) separate Congressional hearings dedicated to tropical disease programs. Favorable Congressional response to the OTA options could have a major impact on the scope of the Institute's tropical disease efforts. A full assessment of the impact on the Institute's tropical disease efforts will be conducted once Congressional action on the OTA options has been taken.

BUDGET PLANS

Question. Given the uncertainties of the FY 1987 budget situation, please describe how you have prioritized your research and training programs.

Answer. We will continue to offer a variety of opportunities to enable U.S. scientists to take advantage of research in other countries, and to provide ways to initiate collaborative relationships with foreign scientists. Since each of our research and research training activities serves a very different purpose, it is difficult to rank them in priority order.

FIC OBJECTIVES

Question. How do the international activities of the Fogarty International Center relate to the objectives of the other institutes at the NIH and the overall objectives of the NIH as a whole?

Answer. The FIC, as an integral part of the NIH, supports the overall mission of the agency and its individual institutes by serving as a link between the U.S. and foreign biomedical research communities. It does so in a variety of ways--by sponsoring research fellowships and health scientist exchanges; conducting studies of and supporting conferences on international health issues; administering the NIH Visiting Program and Guest Researcher Program; coordinating and providing management oversight of NIH activities under bilateral S&T agreements; collecting and disseminating information on NIH international activities and foreign biomedical research programs; and representing NIH and maintaining liaison with foreign research organizations and multilateral bodies engaged in health research.

IMPACT OF BUDGET REDUCTION

Question. The President's budget proposal for FY 1987 reduces your budget by $246,000 under FY 1986 appropriated levels. Gramm-Rudman-Hollings, if triggered, could reduce your budget even further--maybe by as much as 20 percent. Can you give us some idea of the impact of these reductions of the kinds of research that would be stopped or lost?

Answer. A further 20 percent cut, would affect many of our programs to such an extent that we would not be able to mount a viable activity in some of them and they would be necessarily eliminated.

Question. What impact might this have on the health of our citizens five and ten years down the road?

Answer. The impact of these cuts on the health of our citizens five or ten years hence is difficult to assess since much of the research we support directly or stimulate through our bilateral activities is broad based and not specifically oriented towards a particular disease. Nevertheless, we are convinced that without the ability to interact with leading scientists in other

parts of the world, the pace of discovery of new medical and research findings will be slowed significantly to the detriment of the public health of the nation.

Question. Can you discuss your contingency plans if these massive budget cuts should come to pass?

Answer. At the present time we have not developed contingency plans.

Question. If the automatic provisions of Gramm-Rudman-Hollings are triggered in FY 1987, your institute may well have its budget reduced by 20-25 percent. Have you prepared a contingency plan in the event Gramm-Rudman-Hollings becomes a reality? If so, please send a copy of your plans to this committee.

Answer. We have not developed a specific contingency plan.

Question. If cuts of this magnitude become a reality, how will they be distributed?

Answer. Cuts of this magnitude would almost certainly affect all programs and activities with the likely elimination of lower priority activities altogether.

Question. Please list the Research Programs of the highest priority that should not be cut and why.

Answer. Our highest priority is the International Research Fellowship program since it provides a source of bright, young foreign investigators to domestic laboratories and begins a process of research collaboration that lasts long after the fellow returns to his or her home country. We believe that this collaboration forms the basis of international cooperation in biomedical scientific research that is of great benefit both to the United States and the rest of the world.

Questions Submitted by Senator William Proxmire

RESEARCH ADVANCES IN THE SOVIET UNION

Question. Dr. Wallace, your prepared remarks refer to the importance of being aware of research advances taking place in the Soviet Union. With a fall in the average life span and a medical care system that apparently leaves a great deal to be desired, the Soviet Union seems to be an unlikely source for information on research advances. What advances have taken place in the Soviet Union over the past year?

Answer. Although the Soviet health care system is not as sophisticated as ours, the USSR is quite advanced in several areas of biomedical research, such as development and clinical applications of laser technology, basic research on the myocardium, development of new drugs to treat cardiovascular disease and cancer, and biobehavioral research. U.S. scientists have gained valuable insights and technology through cooperation under the US-USSR Health Agreement.

Laser technology as applied to vision research is a case in point. The Soviets provided the National Eye Institute with the technology to build the first Q-switch laser in the U.S. This laser, which was developed in the USSR by a Nobel laureate in physics for use in vision disorders, is considered to be a better clinical tool than the argon laser pioneered in this country.

Soviet scientists have made two recent contributions to research on myocardial metabolism; first, the use of liposomes for delivery and targeting of drugs to damaged heart muscle following a heart attack; and second, basic research on the production and identification of monoclonal antibodies to cell surface constituents in heart and lung cells. The latter technology will have wide-ranging application to the study of platelet adhesion, atherosclerotic plaque formation, and proteins that are important in cardiovascular disease. Other Soviet advances in cardiovascular disease research include the development of a unique experimental technique for basic research on arrhythmia and the development of a series of antiarrhythmic drugs.

Finally, Soviet science has a historical tradition of biobehavioral research that is of considerable interest to U.S. scientists. Recent examples are: the development of biobehavioral approaches to the control of hypertension; and studies relating social behavior and cardiovascular activity to the development of hypertension.

GORGAS MEMORIAL INSTITUTE

Question. Dr. Wallace, on page 6 of your prepared statement you say you are urging the Gorgas Memorial Institute to "develop additional sources of funding so that the Laboratory may continue to be an important resource for the United States". What support are you giving the Institute in this effort and how successful has the Institute been in developing outside funding.

Answer. As an agency of the federal government we cannot assist the Gorgas Memorial Institute directly in their private fund raising activities other than by encouraging them to pursue these efforts as vigorously as possible. Unfortunately, their efforts to date to attract private contributions have not been too successful. Nevertheless, GMI continues to supplement its core funding by successfully competing for research grant funds.

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NATIONAL LIBRARY OF MEDICINE

STATEMENT OF DR. DONALD LINDBERG, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

KENT A. SMITH, DEPUTY DIRECTOR, NATIONAL LIBRARY OF MEDICINE

OPENING REMARKS

Senator WEICKER. Next we will hear from Dr. Donald Lindberg, Director of the National Library of Medicine. The library is the Nation's primary source for biomedical information and is in the forefront in developing technology to distribute that information.

Dr. Lindberg, nice to have you with us. Please proceed.

Dr. LINDBERG. Thank you, Mr. Chairman.

It is a special pleasure for me to appear before you during this, the 150th anniversary of the National Library of Medicine. We are honored that you and your colleagues have enacted a joint resolution designating 1986 to be the sesquicentennial year of the National Library of Medicine.

NLM stands now as the world's preeminent medical library, a tribute to the foresight of past generations of health professionals and to the U.S. Congress. Service is based on the library's immense collection of more than 3.5 million items that are available through both library and electronic networks to health practitioners no matter where they practice.

Overseas users access the NLM's data bases either by satellite telecommunications with the United States or by access to 1 of the 14 overseas MEDLARS Centers.

Mr. Chairman, the pace of development of new knowledge and better treatment is fast nowadays. Indeed the generous funding by Congress of NIH is one of the major reasons for these spectacular advances. The myriads of books and papers that describe such discoveries must be collected, organized, indexed, and made available to health care practitioners as quickly as possible where they need them, or else the patients won't benefit from the improved knowledge.

NLM does this job quite well right now, but I should give a few words about the future. The coming years will see dramatic changes in the nature and quality of the information required for high level quality

of medical practice. We at NLM are preparing ourselves for those changes and advances that the next 20 years hold for us.

I would like to mention four or five aspects of that preparation.

First, a formal 20-year plan is being drawn up for the library by the Board of Regents, with the help of distinguished experts from throughout the country. I shall be happy to present this to you for the next meeting.

Second, we are working with the American Medical Association and other institutions to develop a unified medical language system.

Third, we continue to encourage and support the development at advanced medical centers of IAIMS, the integrated academic information management systems.

Fourth, we continue our intramural research and extramural support of medical informatics. This is the multidisciplinary field that seeks to provide a solid scientific and theoretical basis for the practical computer applications in medicine. Indeed, there have been a number of practical accomplishments from this field, and we expect even more important developments in the future.

With respect to that field, more research is, in fact, needed. One of the important reasons for this is the recent exciting advances in molecular biology. We note that the ambitious goals, lately announced, to understand the origin of cancer through molecular biology techniques, and to map the entire human genome are totally dependent upon major future advances in medical informatics.

In other words, the future information systems to support discovery in biogenetics and molecular biology are as essential as the much to be desired breakthroughs at the laboratory bench level and in the clinic.

Fifth, we have completed a preservation study so that we can avoid the loss of that portion of the NLM collection that is in immediate danger because of deteriorating acid paper.

In summary, Mr. Chairman, we are maintaining the vital information services that the health care community has come to rely on, while at the same time, we feel we are positioning ourselves to take maximum advantages of the new technologies.

Although perhaps too little recognized, the library's products and services are a vital link in the chain that connects the biomedical research paid for by tax dollars with the good health care that the taxpayers expect to receive.

Our request is in the amount of $56,408,000, and I would be pleased to answer any questions that you might have. Thank you.

PREPARED STATEMENT

Senator WEICKER. Thank you. We will place your statement in its entirety in the record.

[The statement follows:]

Statement of Dr. Donald Lindberg

Mr. Chairman and distinguished members. It is a special pleasure for me to appear before you during this, the NLM's 150th anniversary. We are honored that you and your colleagues have enacted a Joint Resolution designating 1986 as the Sesquicentennial Year of the National Library of Medicine. President Reagan, in issuing a proclamation about the Library, said: "American citizens, for whom the health of their loved ones is always a primary concern, can take great pride in their National Library of Medicine."

Mr. Chairman, for 150 years, the Library has quietly gone about the business of providing medical information to America's health professionals. Today it stands as the world's pre-eminent medical library, a tribute to the foresight of past generations of health professionals and legislators.

From a handful of books in the Surgeon General's office to a collection of 3.5 million housed in two modern buildings on the campus of the National Institutes of Health, the National Library of Medicine is an institution in which all American citizens can take pride. The last two decades, especially, have been a period of unparalleled expansion in the Library's responsibilities. A series of challenges in health communications has been met with a series of prudent and successful responses:

- Deteriorating medical libraries and their inability to meet the needs of the biomedical community led to the Congress enacting the Medical Library Assistance Act of 1965. This law not only improved the state of medical libraries but made possible the creation of a Regional Medical Library Network for disseminating biomedical information that has served the Nation well for 20 years.

- Concern with the quality of the environment led a Presidential commission to recommend a special Federal toxicology information program. This was established at the Library in 1967.

- The potential of new computer and communications technologies led the Congress to call for a major research and development program at the Library: the Lister Hill National Center for Biomedical Communications. Since 1968, this organization has played a key role in improving information services for medical research, education, and health care delivery.

- The Library's pioneering computerized medical information system--MEDLARS--went online in 1971 and now provides 3 million searches each year to some 4,000 institutions that are members of NLM's network. Later this year, we will add our 6 millionth record to the database.

The Challenge of the 80's and Beyond

There can be no doubt that the information needs of the medical profession will change dramatically in the years ahead. These changes will spring from new information generated by our national investment in research and also from the opportunities afforded us by evolving computer and communications technologies. The National Library of Medicine is today engaged in a series of activities that will allow the Library to shape, rather than be shaped by, these changes.

First, a formal 20-year plan is being developed for the Library with the assistance of panels of experts from around the Nation. These experts are ranging widely in considering how the Library should address the future: from the role of traditional collections and services, to computerized banks of actual scientific data (as opposed to bibliographic information), to Medical Informatics research and how it can influence medical education and health care. The plan will be presented to the Library's Board of Regents later this year.

Second, the Library, with the encouragement of the Congress, has embarked on an ambitious project to develop a Unified Medical Language System. The lack of a practical common terminology greatly impedes the efficient retrieval of biomedical information. The system now under development will permit a health care professional or scientist to move smoothly from one data source or file to another in order to gather information pertinent to the particular problem of a patient. The Library's effort to develop such a system is a joint one with the American Medical Association, university research groups, scientific professional societies, and Federal experts. Essential to any such integrating system is a way for the individual physician or scientist to dial directly into NLM's services. A new microcomputer interface that will do just that has already been developed and is now being made available to those who wish to have direct access to the Library's computers.

The implementation of a Unified Medical Language System would help to accelerate progress in other developments of national importance. These include the Integrated Academic Information Management System (IAIMS) and programs to improve the state of Medical Informatics. The IAIMS concept is to use computer and communications technologies to create systems in

academic centers that integrate a variety of information in support of health research, education, patient care, and management. IAIMS grants are designed to produce exemplary, advanced, prototype systems at a small number of outstanding American medical centers. Several such centers have been funded and it is hoped that they will serve as models for others.

Medical Informatics, another beneficiary of the Unified Medical Language System, is a multidisciplinary research field involving the integration of computer and information sciences, medicine, engineering, and management science. This work provides the growing scientific and theoretical basis for the application of computers and automated information systems in medicine. One product of such research will be computerized systems with which human users can consult interactively, much in the same way that physicians and scientists now consult with their colleagues.

Preservation Initiative

The National Library of Medicine's primary function is its statutory responsibility to acquire and preserve library materials pertinent to medicine. Although the Library devotes significant efforts to carrying out its preservation responsibilities, the majority of library materials in existence today are works printed on high-acid content paper that is destined to disintegrate. NLM faces the inevitable loss of much of its collection unless preventive action is taken immediately. Data gathered by an NLM Preservation Planning Team show that 8.8% or 113,000 volumes in the NLM collection are so brittle that they must be copied to another medium to ensure long-term preservation of the information they contain. The remaining 91.2% of the volumes must be deacidified to prevent rapid deterioration. This is a problem faced by all large research libraries and we are optimistic that the Library of Congress may allow NLM to use its planned mass deacidification facility when that facility becomes operational in the next few years. Additional funds provided by Congress in FY 1986 will allow NLM to award a major contract for the microfilming of deteriorated materials.

Intramural Programs

Library Operations is the component responsible for NLM's basic mission--to build, maintain, and provide access to the world's largest collection of biomedical literature in support of progress in medicine and the improvement of public health. In FY 1985, the NLM added some 239,000 items to the collection and for the first time acquired a limited number of software packages. MEDLARS, NLM's computerized database system, not only provides online searching services, but produces many

bibliographic publications, such as Index Medicus, a major index to 2,730 biomedical journals, and specialized literature searches on such subjects as acquired immunodeficiency syndrome (AIDS), smoking and health, and child abuse. In addition to providing access to biomedical literature through publications and online databases, NLM helps health professionals to obtain copies of documents in the collection.

The Lister Hill National Center for Biomedical Communications is the intramural research and development component of the Library. The Center is performing research in a number of promising areas. One of these is the use of optical discs for electronic document preservation. This technology affords the ability to store a wide range of material. There are some documents in which it is not suitable, but in others it's actually possible to improve the quality of its electronic images over that of the original documents. These systems have the ability for random access. Information is automatically retrieved by using existing citation databases as directories. Other areas of research include: research in knowledge representation with computer-based systems; examining methodologies for electronically organizing machine-readable databases to increase the productivity of NLM's indexing and cataloging; and developing prototype computer-assisted instructional materials for medical education.

The Toxicology Information Program (TIP) has two primary objectives: to create computerized toxicology databases and to provide toxicology information products and services to the scientific community. These services are made available through a variety of online information retrieval files, through query response, and interagency collaborative projects. Work continues on developing the microcomputer workstation that is to be used for retrieving information needed in responding to emergencies involving hazardous chemicals. Also a version of the Chemical Substances Information Network software has been developed called micro-CSIN for the use of the workstation.

Summary

The mission of the National Library of Medicine--the rapid and efficient dissemination of biomedical information--is an integral part of the research process. Without dissemination, the fruits of research have little value. The Library's innovative programs, many of which I have described for you today, exploit the latest advances in technology and information science expertise and thus assist the nation's biomedical research and health care apparatus to operate more efficiently and effectively.

Mr. Chairman, the request for the National Library of Medicine for FY 1987 is $56,408,000, an increase of $1,086,000 from the FY 1986 adjusted appropriation level. I shall be pleased to answer questions and supply additional information for the record.

Biography of Dr. Donald Lindberg

September 21, 1933. New York, New York

Education: A.B., Biology, Amherst College, magna cum laude, 1954; M.D., College of Physicians and Surgeons; Columbia University, 1958; Sc.D., Amherst College, (hon. caus.) 1979.

Professional History: 1984-present, Director, National Library of Medicine; 1971-1984, Director, Information Science Group, University of Missouri School of Medicine; 1969-1984, Professor of Pathology, University of Missouri School of Medicine; 1976-1980, Director, Health Services Research Center with Special Emphasis Health Care Technology Center, University of Missouri-Columbia; 1972-1973, Consultant for Health Sciences to Vice President for Academic Affairs; 1969-1971, Professor and Chairman, Department of Information Science, University of Missouri School of Library and Information Science; 1970-1971, Staff, Vice President for Academic Affairs, University of Missouri; 1967-1970, Director, Regional Medical Program Information Systems; 1968-1970, Staff, Executive Director for Health Affairs, University of Missouri; 1962-1970, Director, Medical Center Computer Program, University of Missouri; 1967-1969, Director, Missouri Regional Automated Electrocardiography System; 1966-1969, Associate Professor of Pathology, University of Missouri School of Medicine; 1963-1966, Assistant Professor of Pathology University of Missouri School of Medicine; 1962-1963, Instructor in Pathology, University of Missouri School of Medicine; 1960-1963, Director, Diagnostic Microbiology Laboratory, University of Missouri Medical Center; 1960-1962, Resident Physician in Pathology, University of Missouri School of Medicine; 1959-1960, Assistant Resident in Pathology, Columbia-Presbyterian Medical Center; 1958-1960, Assistant in Pathology, Columbia University College of Physicians and Surgeons; 1958-1959, Intern in Pathology, Columbia-Presbyterian Medical Center; June 1955-Sept. 1955, June 1954-Sept. 1954, Research Assistant to Dr. O.E. Schotte, Amherst College.

Honors: Phi Beta Kappa; Simpson Fellow of Amherst College (1954-55); Markle Scholar in Academic Medicine (1964-69).

Professional Memberships: Sigma Xi; American Society of Clinical Pathologists; College of American Pathologists

(Telecommunication Network Committee, Committee on Emerging Technology); Missouri State Medical Association; American Association for Advancement of Science; Association for Computing Machines (SIGBIO); Salutis Unitas; American Association for Medical Systems and Informatics, Board of Directors; Symposium on Computer Applications in Medical Care, Board of Directors; National Board of Medical Examiners, Board Member; Washington Society for the History of Medicine; Editor: Information Methods in Medicine, Lecture Notes in Medical Informatics, and Journal of Medical Systems; National Academy of Practice in Medicine Distinguished Practitioner; Computer Science and Engineering Board, Institute of Medicine, National Academy of Science (1971-1974); U.S. Representative to International Medical Informatics Association, and Trustee (1975-1984).

REGIONAL MEDICAL LIBRARY NETWORK

Senator WEICKER. Senator Proxmire.

Senator PROXMIRE. Dr. Lindberg, last year's justifications indicated that the regional medical library network comprised over 3,000 basic health sciences libraries in hospitals and health-related institutions. According to this year's justifications that number has increased to over 4,000 libraries. That is a tremendous increase—an increase of one-third.

Can you tell us what contributed to such a phenomenal growth in the system?

Dr. LINDBERG. Yes, sir; I can't claim that we are out there putting one brick on another and building 1,000 libraries, but they did more actively participate in our system during the course of the last year. One particular new aspect that facilitated this is a system called DOCLINE. The interlibrary loans exchanged between the network libraries have been done through telephones, teletypes, via a formal hierarchy. During the last year, NLM has started a really super system that lets all of those requests be handled by our computer, routing the request to the nearest local library. In other words, we know what serial titles are held at which library, and we know their lending policies, we know which is closest. That particular system has had such a phenomenally warm reception that, in fact, we have integrated more fully an additional 1,100 libraries in the network.

Senator PROXMIRE. What sort of growth do you anticipate in the next 12 months?

Dr. LINDBERG. We are thinking that by the end of this year that we will have accounted for approximately 70 percent of the interlibrary loans countrywide. Then, of course, getting the last 30 percent will take a few more years.

Senator PROXMIRE. Do you expect a 10-percent increase in the network next year?

Dr. LINDBERG. Yes.

LIBRARY SERVICES

Senator PROXMIRE. On page 377 of your justifications, you state: "Hours of service to the public and timeliness of availability of the latest research results in NLM's computerized data bases would be maintained to the best of our ability."

Can you tell us what the phrase "to the best of our ability" means? For example, do you believe that it will be necessary to reduce hours of service to the public?

Dr. LINDBERG. That is one of the things that we are considering, but certainly we will make every effort to keep the services accurate, prompt, and complete.

Before we would shut down onsite services at the library and reduce the hours, we would reduce the acquisitions somewhat taking into account the escalation of costs of those as compared to the funding. We would probably have to process the cataloging and indexing a little differently and more slowly.

Again, we would always hope to have the most important reports done first. Preservation would have to be cut back a bit as well. Only as a kind of a last resort would we want to shut down the hours because as we can tell from the newspaper this morning, people resent that very bitterly.

Senator PROXMIRE. So you think there is a good chance you will not have to reduce hours of service, that you can achieve reductions by taking these other measures.

Dr. LINDBERG. We hope we won't. To tell you the truth, the reduction in FTE's would urge us more to reducing hours than the dollars. That is quite hurtful in a service-based operation.

NLM SESQUICENTENNIAL

Senator PROXMIRE. You indicate on page 381 of your justifications: "To ensure that the library's services are better known and their contribution to society maximized, a series of sesquicentennial activities has been planned throughout the year."

Can you tell us how much of your current budget you are devoting to these activities?

Dr. LINDBERG. I think that I am going to ask my deputy, Kent Smith, to give you his closest estimate.

Mr. SMITH. Approximately $100,000.

DEMAND FOR NLM SERVICES

Senator PROXMIRE. Are you at all concerned that these activities will stimulate a public demand that you will be unable to meet in 1987?

Dr. LINDBERG. No, sir; I think that the computerized services need to be more widely recognized and used, particularly by health professionals; part of that problem is because of a lack of training. In other words, the people who graduated from medical school 20 years ago had no opportunity to learn how to use the new electronic system.

Senator PROXMIRE. I agree wholeheartedly on that. My question, though, is whether or not you will be able to meet the demand that you stimulate?

Dr. LINDBERG. I think we can. The capacity of the computer system is really tremendous. If one doesn't have to create a new system, but only increase the volume on it, we will be able to do that. I should say that in the last year, we went from a restricted usage to 24 hours a day, 7 days a week.

We used to operate under the assumption that emergencies stopped at 9 p.m. Washington time, and we realized that that wasn't the proper assumption. We were able to increase the hours through the clever work, really, of the staff. This was accomplished without any extra people, without any extra dollars, and without any extra hardware, but just by a more clever arrangement of the system to take it to 24 hours.

Senator PROXMIRE. You indicated that you might have to—you are going to resist it, and you thought you might be able to avoid it—but that you might have to cut back hours of service.

Dr. LINDBERG. We would never cut back the 24-hour computer service. We might consider, only as a last step, to close down the reading rooms to the public.

Senator PROXMIRE. But you feel you can meet whatever additional demand is brought on by the sesquicentennial?

Dr. LINDBERG. Yes; if I could tell you one other way. I guess it is just a technological fix, but it is still something that we are rather proud of. We have created a system with a user-friendly front-end, so that doctors who have personal computers can take this disk and dial the NLM themselves, bypassing the libraries and even the consulting systems. They can make their own inquiries.

Because of the way the system is arranged, the time and the costs are reduced by about 40 percent. One just gets on and off of the system much more efficiently. That in itself increases our capacity substantially.

So, essentially, we were able to discover technological fixes to technological problems. What we can't get around is the educational problems, those are the more difficult and the more expensive.

Senator PROXMIRE. The last time a Lindberg was this farseeing was 1927. [General laughter.]

Thank you, Mr. Chairman.

Senator WEICKER. I just want to emphasize, you don't feel that you are going to have to retreat on your 24-hour service.

Dr. LINDBERG. No; definitely not.

Senator WEICKER. At least under the 1987 budget.

Dr. LINDBERG. At least under the 1987 budget, not modified, if that is the worst that happens to us. There are many other things that won't happen, but we won't do that.

Senator WEICKER. I agree with you.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

I have further questions for response to the record. Thank you very much.

Dr. LINDBERG. Thank you, sir.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

NEW TECHNOLOGIES AND TRAINING

Question. We have been talking about the development of new medical information technologies that would benefit both patient care and medical research. Are there enough medically competent individuals who can fully utilize the new and developing technologies?

Answer. The National Library of Medicine (NLM) currently supports five extramural awards for research training in medical informatics. NLM is the sole federal source for such important activities. The amount budgeted for this program in both FY 1986 and FY 1987 is approximately $1.2 million, and supports about 28 trainees.

Question. Are we training enough individuals to meet our future needs in this area?

Answer. Clearly, needs in medical informatics training are increasing, and will continue to increase in the future. Ten years ago, in FY 1976, 91 trainees were supported, so I would have to say the situation is deteriorating in terms of numbers. Another indicator may be a recent survey of graduating physicians which pinpointed insufficient training in computers as the number one criticism of medical school curricula.

Question. In your professional judgment, what should we be doing in the area of training?

Answer. I believe that an optimal program of research training in medical informatics would support approximately 60 trainees at a minimum of ten academic centers nationwide.

COMPUTER TECHNOLOGY/PATIENT CARE

Question. Please describe your long-range plans to allow health professionals to keep up with advances in computer and information technology that would be used to benefit patients.

Answer. With the assistance of five distinguished panels of experts, the Library is developing a long-range plan. This plan, which I will be able to present to you at next year's hearing, will be a blueprint for the Library's programs and activities for the next 20 years. In this way, we expect to meet the challenge of changing information needs and technologies.

Right now, we have a number of programs and services that help health professionals utilize the most recent developments in computer and information science technology. Included are:

- o Integrated Academic Information Management Systems (IAIMS)
- o Unified Medical Language System
- o GRATEFUL MED software
- o Videodisc-based CAI (computer-assisted instruction) systems
- o 24 hour MEDLARS service

Question. How much are you budgeting in FY 1987 for this activity, and, in your professional judgment, is this enough to allow for a consistent effort in this area?

Answer. Broadly speaking, the entire budget of the Lister Hill National Center for Biomedical Communications (LHNCBC) is directed toward utilizing the latest advances in computer and communications technologies for improved medical education, patient care, and research. The LHNCBC FY 1987 budget level is $9,259,000, and includes approximately $1,000,000 for the development of a Unified Medical Language System and $500,000 for videodisc-based computer-assisted instructional systems. In my professional judgment, a budget for the LHNCBC in FY 1987 that is consistent with the research opportunities available would provide $300,000 for increased costs, and an addition of $3,000,000 to the Unified Medical Language System project.

The Integrated Academic Information Management Systems (IAIMS) program of extramural grants is budgeted at $2,200,000 in FY 1987. Presently, this program is in its second phase--development of prototypes. My professional judgment is that an additional $3,100,000 could be well utilized to begin the third and final phase of the program--implementation of model systems.

GRATEFUL MED is a user friendly software package which enables individual health professionals to access MEDLARS easily and efficiently using their own personal computers and modems. It has already been developed, and is now available for distribution nationwide through the National Technical Information Service. Twenty-four hour MEDLARS service was inaugurated this past year and requires no additional funding or staff to maintain.

Question. Is there any significant competition from foreign technology in the development of this type of information system?

Answer. Yes, there is. A recent report by the National Academy of Sciences, entitled "Frontiers in Science and Technology," warned that the U.S. must pay greater attention to scientific communication if American science and technology is to remain competitive in the world marketplace. Advances that have already occurred in electronic communications, the report said, offer great potential for eliminating impediments to communication among scientists.

The Academy cited the National Library of Medicine's electronic databases as an important approach for "improving the communication of scientific and technical advances," but noted that much more needs to be done to realize the potential of the new communications technologies.

BASIC AND CLINICAL RESEARCH

Question. Dr. Goldstein has discussed an improved post-stroke treatment that was developed due to strong ties between basic and clinical researchers. I assume that a large part of these strong ties is due to a superior method of communication between the basic and clinical scientists. What can and should be done to improve this communication and, in your professional judgment, are we committing enough of our resources to achieve this end?

Answer. As the question suggests, a great many of the breakthroughs in understanding brain and nervous system function do arise from the remarkable advances in basic research in molecular biology. In other words, the nature of Alzheimer's Disease (and other neurological diseases with familial tendencies) seems to be linked like cancer to the same profound secrets of the nucleic acid molecule of the genes and viruses. Advances in analyzing these complex molecules are reported in the scientific literature and indexed by NLM, helping both researchers and clinicians to use the new knowledge. However, the nature of the data reported is such that ordinary journal publications do not suffice. Additional computer databases derived from the literature have been required. Major systems to store and analyze this rapidly growing knowledge include GENBANK, supported by NIGMS, NCI, NINCDS, DCRT, and NLM. The BIONET system, supported by DRR, is also very important.

These systems have greatly helped discovery in this area. In my professional opinion the new data will, in the near future, greatly exceed the capacity of the present systems. NLM should be investing much more heavily in the

development of advanced systems in molecular biology, because of the great good to be gained by discoveries in neurosciences and cancer and because these systems represent examples of the modern type of computer representations of the scientific literature that NLM will be expected to store in the future.

INFORMATION ACCESS

Question. This Committee has clearly stated that it is important for health care practitioners to be able to acquire accurate information rapidly that they need for diagnosis and patient management. What steps has the National Library of Medicine taken to improve access to biomedical information for health professionals in this country.

Answer. The Library has recently announced the availability of a new user friendly software package--called GRATEFUL MED--which will simplify the searching of our databases. Physicians and other health professionals can now use their personal computers to perform most queries of our databases directly--from their offices or laboratories--without having to know special vocabulary or index terms. This is a very exciting development.

Training on the use of NLM's information systems is available at many locations throughout the country, provided both by NLM staff and selected Regional Medical Libraries. More and more individuals are receiving this training, particularly health professionals most recently. The number of users of our system continues to rise, partly because of our training activities and partly because of the growing number of health care professionals who own their own personal computers.

Thirdly, a nationwide system for interlibrary loan and referrals was recently inaugurated. This system, called DOCLINE, will greatly speed-up the lending process among health science libraries around the country by routing requests for biomedical literature automatically through the NLM-sponsored Regional Medical Library network.

Question. Will your FY 1987 budget request allow you to maintain this service at optimal speed or will there have to be a slowdown in the time new information becomes available?

Answer. We will endeavor to maintain biomedical information services to the best of our ability. However, the FY 1987 request level, although providing modest increases in a very difficult budgetary year, does not fully provide built-in cost increases. Although the rate of reporting research in the published literature is increasing, NLM will

need to reduce the actual acquisition of books and other publications. NLM indexing and cataloging practices, which affect all the nation's medical libraries will be altered and the backlog of unprocessed materials will increase to levels which could delay the availability of the latest research results. Obviously some research results are of more immediate importance than others, for example, drug reactions and toxicological information from chemical spills. We will endeavor to ensure that such results are reported promptly and hope that we will always recognize the most important information.

RESPONSE TO ENVIRONMENTAL EMERGENCIES

Question. I understand that the National Library of Medicine has an information bank that is available to both public and private sector communities in responding to emergencies caused by environmental accidents. How is this activity funded, and in your professional judgment are you requesting enough funds to maintain this data bank at optimal readiness?

Answer. This activity, called the Hazardous Substances Data Bank (HSDB), has been jointly funded by the NLM and by the Environmental Protection Agency (EPA) Superfund Program through the Agency for Toxic Substances and Disease Registry (ATSDR) in DHHS. The peer-reviewed data within the HSDB file is made available to both public and private sector communities through NLM's Toxicology Data Network (TOXNET) system.

NLM has previously received adequate Superfund resources to develop and maintain the HSDB data records and to deliver this information in response to chemical emergency situations.

Question. What impact, if any, will the lapse of the Superfund have on this activity?

Answer. The lapse of Superfund resources in FY 1986 has resulted in a marked decrease in this activity. Failure to provide resources in FY 1987 will seriously damage this database. An attempt will be made to maintain existing records but few if any new chemical records will be entered in the HSDB.

FY 1986 APPROPRIATION INCREASES

Question. The National Library of Medicine received an increase in their FY 1986 appropriation to begin the implementation of a Preservation Initiative and for the development of

the Unified Medical Language System. Please tell us what you plan to accomplish in FY 1986.

Answer. We have begun to implement the recommendations contained in our comprehensive Preservation Plan, which was developed by staff last year. Specifically, a Preservation Section is being established organizationally, and recruitment is underway for its chief. We expect to award a contract to begin on-site microfilming of embrittled materials by summer. Approximately 113,000 volumes in the NLM collection are so brittle that they must be copied to another medium to ensure long-term preservation of the information they contain. Efforts to preserve our special collections, such as rare books and historical films have been accelerated.

The creation of the entire Unified Medical Language System will take five years at a minimum. This is a major development--probably as big as creation of the MEDLARS system itself--and perhaps more difficult because there is no "manual" model to follow.

Even so, the project is well under way. By the end of 1986, we will have completed the following essential initial steps:

1. Systematic analysis of the relationship between the language used in clinical patient records and that used in the NLM thesaurus and that used in the scientific literature.

2. Systematic analysis of the relationship and possible mutual complementarity between the NLM thesaurus, and thesauri and nomenclatures supported by selected professional associations.

3. Establishment of contractual relationships to support joint and coordinated research and development between NLM and the university-based and private sector-based organizations that have the interest and ability to contribute to this project.

4. Creation of the initial tools with which to construct the System. We expect these will include the following:

    a. developmental computer set-up with which to add the new terms to NLM's existing thesaurus and to display graphically the relationships between the medical concepts these terms represent;

b. creation of bench-mark data sets for testing system improvements, representing clinical diagnosis and treatment records and problems, published scientific literature, and health sciences educational requirements;

c. development of a provisional (prototype) representation for computer storage of the relationships essential for the System; and

d. development of a provisional model for a standardized summary for scientific articles.

Question. What has been budgeted for these two programs in FY 1987?

Answer. For the new preservation initiative, $600,000 is budgeted at the FY 1987 request level. The comparable number for the Unified Medical Language System is $1,000,000.

Question. In your professional judgment, will this amount of funding be enough to keep these two high priority programs on track, and if not, how much will you need?

Answer. Budgetary constraints aside, in my professional judgment the optimal level for the preservation initiative would be $1,200,000--the same as the Preservation Plan recommends--and development of a Unified Medical Language System would be $4,000,000 in FY 1987.

FUTURE PLANS

Question. What kind of long-range planning are you doing for the National Library of Medicine?

Answer. The revolution in information management effected by computer and communication technology has created enormous challenges. To ensure these challenges are met, the NLM Board of Regents has embarked on a long-range planning process for NLM that, in addition to producing a blueprint for the future, is serving as a sounding board for the varied constituencies to advise the Library about the direction of its programs. Planning panels composed of experts from around the nation have been convened and are developing recommendations and priorities in five broad areas that encompass current activities and provide a framework for considering the future. These are: building and organizing the Library's collection; locating and gaining access to medical and scientific literature; obtaining factual information from data-

bases; Medical Informatics; and assisting health professional education through information technology. The plan is expected to be completed and presented to the NLM Board of Regents for their consideration this year. This plan will contain a vision of the role of the NLM in 20 years, and the resources required.

Question. Can you describe what the National Library of Medicine should be like 20 years down the road?

Answer. As Director of NLM, I certainly have my own views as to what the "library" of the future should be. There are, however, several areas already apparent on which all agree.

1. The NLM of 20 years hence will still be expected to provide leadership and coordination to the nation's biomedical communications system through the Regional Medical Library network. This system has already become a model for the world.

2. NLM will still be expected to provide leadership and a national focus for research and training in medical informatics. This field will before this time have matured as the source of theoretical and scientific principles on which practical computer information applications in health care are based.

3. The actual work and the collections of NLM will still include books and other reprint materials, but a much greater percentage of the knowledge needed for patient care and for scientific discovery will be organized and distributed by NLM in forms that can be read directly by computers.

I'd like to defer completing the answer to this question until our outside panels of experts can give us their answers. We expect their report by the end of this year. I will be most pleased to share it with you at that time.

Question. Are we investing enough resources to allow you to realize your long-range plan?

Answer. We will be able to compare actual resources available to recommended levels when the long-range plan is completed by the end of this year.

COLLECTION DEVELOPMENT

Question. What impact will the FY 1987 budget have on collection development at the National Library of Medicine?

Answer. In fiscal year 1985, NLM obligated $2,129,000 for acquisition of literature. We estimate that literature costs are increasing by 10-12% per year. Assuming the lower rate, $2,576,000 would be required in FY 1987 to maintain our acquisition rate. The amount budgeted at the President's request level is $2,175,000.

Question. Will you be cutting back on acquisitions, cataloging, preservation, indexing, or other aspects of bibliographic control? To what degree?

Answer. All of the activities listed will have to be reduced somewhat to accommodate the FY 1987 budget. We will try our best to minimize the impact of these reductions upon our services to the public, by attempting to prioritize which articles and books are most important to acquire, catalog, index, and input onto our computerized system. We hope we will make the correct decisions concerning which medical information to select and process most quickly, and which we can afford to exclude or process less rapidly.

INTRAMURAL PROGRAM

Question. The increase requested for your intramural program is not enough to keep up with inflation, and the amount is actually a 2% decrease from the FY 1986 appropriated level. Since the Intramural Program represents about two-thirds of your budget, what key activities will need to be restricted?

Answer. Because we were directed to reduce each of our program activities by 4.3%, biomedical information services, which constitute about three-quarters of our total intramural budget, necessarily take the largest dollar reduction. Some of the service-related reductions that will be required include:

- Reduced acquisition of new materials; literature costs are increasing by 10-12% per year.
- Alter cataloging and indexing practices--which affect all the nation's medical libraries--creating a backlog of unprocessed materials which may delay the availability of the latest research results.
- Collection maintenance, and the preservation initiative begun this year, will be reduced. Approximately 113,000 volumes in our collection are severely embrittled; this number is increasing.
- Toxicology Information Program activities will also be decreased. This decrease is amplified by a

reduction in Superfund support, resulting in a significant diminution in our ability to maintain and enhance toxicological databases.

Research and development in the application of computer and information sciences to problems of biomedical communications, conducted by the Lister Hill National Center for Biomedical Communications, will also be restricted.

OREGON HEALTH SCIENCES UNIVERSITY

Question. What is the status of the planning award for the Biomedical Information and Communications Center at the Oregon Health Sciences University?

Answer. In January 1984, NLM awarded a planning contract to Oregon Health Sciences University (OHSU) for $495,000. OHSU has requested, and NLM has agreed to, extensions of this planning contract. The current timetable calls for OHSU to submit a plan for the development of the center to NLM by June 1986.

GRAMM-RUDMAN-HOLLINGS SEQUESTER

Question. I understand that you have been required to distribute the 4.3% sequestering of Gramm-Rudman-Hollings by budget mechanism. If you had the flexibility to allocate the reductions among your programs in another way, would you shift these funds? Please explain why your choice of distribution would produce better management results.

Answer. As a starting point, the NLM was instructed to allocate the Gramm-Rudman-Hollings reduction equally by program activity. But we retain a great degree of flexibility to reallocate funds, if necessary. Over 80 percent of our program falls within a single Gramm-Rudman-Hollings activity. In order to reduce the impact on library services, we expect to cut other NLM programs. The provision of basic library services to the nation's biomedical community is NLM's highest priority.

IMPACT OF BUDGET REDUCTION

Question. The President's budget proposal for FY 1987 reduces your budget by $1,400,000 under FY 1986 appropriated levels. Gramm-Rudman-Hollings, if triggered, could reduce your budget even further--maybe by as much as 20 percent.

I've known this would reduce the number of grants, possibly the size of grants, centers, training, etc., etc. Can you give us some idea of the impact of these reductions on the kinds of research that would be stopped or lost?

Answer. The President's Budget was developed within overall deficit targets that would preclude the need for sequestration in FY 1987. Clearly, a reduction of the magnitude you mentioned would have a severe impact on all of the Library's programs, both research and service. Such reductions would warrant careful review of all programs and would possibly require eliminating certain programs and activities altogether.

Question. What impact might this have on the health of our citizens five and ten years down the road?

Answer. The dissemination of biomedical information is an integral part of the research process. Without dissemination, the fruits of research have little value. Degradation of the quality and timeliness of NLM's biomedical information services would certainly adversely affect both research and patient care in this country.

Question. Can you discuss your contingency plans if these massive budget cuts should come to pass?

Answer. No contingency plans have been developed at this time.

FULL-TIME EQUIVALENTS

Question. The Library's FY 1986 full-time equivalent (FTE) ceiling of 504 is 27 less than FY 1985. How has this reduction affected the National Library of Medicine's ability to provide high quality biomedical information services to this nation's research scientists and health care delivery professionals?

Answer. Over a two-year period FTEs have been reduced from 544 to 504, a reduction of 7%. This reduction has had an effect on our ability to maintain high quality services. For example, our cataloging backlog is now actually increasing and several cataloger positions have gone unfilled due to the hiring limitations.

CUTS

Question. What specific activities did you reduce in order to absorb the Gramm-Rudman-Hollings sequestration in FY 1986? Have you had to reduce your hours of service to the public?

Answer. Although the 4.3 percent sequestration has been applied evenly across all programs and mechanisms at NIH, the Institute Directors do have the authority and flexibility to reallocate funds within existing reprogramming rules to

meet the most critical program objectives, so long as they do not deviate from the few programs, projects, and activities formally reported to the Congress under the Gramm-Rudman-Hollings procedures. For the Library these activities are, assistance to medical libraries, work on a Unified Medical Language System, preservation of library materials, Medical Informatics and basic library services.

We have tried very hard to avoid reducing our hours of service to the public. Even though NLM is primarily a "library of libraries," we feel that public accessibility is an important activity. So far, we have not reduced hours, but further reductions will likely make this necessary.

PLANNING

Question. In the course of your long-range planning process, what areas have emerged as being of particular priority to your varied constituencies? Will this budget allow you to respond appropriately?

Answer. It is perhaps premature to discuss the recommendations of our five panels of outside experts who are presently engaged in preparing the long-range plan document. As I've mentioned, the plan itself will be completed by year's end, and I will be pleased to share it with you at that time. Nonetheless, based on discussions to date, I am pleased to report that the panels have expressed support for the programs that we at the Library, and you in the Congress, have given a high priority in recent years. Among these are the development of a Unified Medical Language System, preservation of the Library's collection, Medical Informatics research and research training, and development of Integrated Academic Information Management Systems (IAIMS).

The President's request for FY 1987 will permit us to maintain support for each of these programs at approximately the same level of support as in FY 1986. Any new initiatives or proposed expansions of ongoing projects which may be identified in the long-range plan would be deferred.

GRAMM-RUDMAN-HOLLINGS IN FY 1987

Question. If the automatic provisions of Gramm-Rudman-Hollings are triggered in FY 1987, your Institute may well have its budget reduced by 20-25%. Have you prepared a contingency plan in the event Gramm-Rudman-Hollings becomes reality? If so, please send a copy of your plans to this committee.

Answer. We have no contingency plan for cuts of the magnitude you mentioned. Specific decisions will require

careful analysis and consideration by the NLM Board of Regents.

Question. If cuts of this magnitude become reality, how will they be distributed:

1. Intramural vs. extramural programs;

2. Peer review system;
   would number of site visits be reduced?
   would travel to NIH to study section meetings be affected?

3. Would NIH employees have to be furloughed?

4. What major programs would have to be cut back?

Answer. Until a review of all programs and activities is complete, it is not possible to identify those programs that would be cut at the levels you mentioned, but clearly all activities would be very significantly reduced.

Question. Please list the research programs of the highest priority that should not be cut and why.

Answer. Our highest priority is attempting to continue to provide basic biomedical library services, including our MEDLARS system. Unfortunately, such services would undoubtedly suffer a degradation of quality, timeliness and completeness.

OFFICE OF THE DIRECTOR

BUILDINGS AND FACILITIES

STATEMENT OF EDWARD E. NICHOLAS, JR., ACTING ASSOCIATE DIRECTOR FOR ADMINISTRATION

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

DR. EDWIN D. BECKER, ASSOCIATE DIRECTOR FOR RESEARCH SERVICES, NATIONAL INSTITUTES OF HEALTH

STORM WHALEY, ASSOCIATE DIRECTOR FOR COMMUNICATIONS, NATIONAL INSTITUTES OF HEALTH

PREPARED STATEMENTS

Senator WEICKER. Now, we will hear from the Office of the Director of NIH, and that will include a discussion of the appropriation for buildings and facilities.

I gather that the principal witness for both of these appropriations is Mr. Edward Nicholas, Jr., Acting Associate Director for Administration, and Mr. Storm Whaley, Director of Communications for the National Institutes of Health will discuss the plans for the celebration of the NIH centennial.

Mr. Nicholas, why don't you start off, and we will deal with this entirely, and then we will get to this other discussion.

We will place your statement and that of Storm Whaley in the record and then you may proceed.

[The statements follow:]

STATEMENT OF EDWARD E. NICHOLAS, JR.

I am pleased to have the opportunity to discuss with the Committee the Office of the Director and the Buildings and Facilities appropriations of the NIH.

Office of the Director

This appropriation funds those components of the central administration that are primarily responsible for the development of NIH-wide policy and procedures and the coordination of program activities. The Immediate Office of the Director includes the principal associates of the Director and staff officers who provide advice and assistance in the administration and coordination of the intramural and extramural research programs of the Bureaus, Institutes and Divisions. Other offices provide leadership in such areas as equal opportunity, program planning and evaluation, disease prevention, medical applications of research, public and scientific communication, protection from research risks, management analysis and review, contracts and grant administration, and budget and personnel management.

Mr. Chairman, the appropriation request for 1987 for the Office of the Director is $36,701,000.

Buildings and Facilities

The second appropriation for which I am testifying is the Buildings and Facilities appropriation that provides funds for the design, construction, and repair and improvement of clinical and laboratory buildings and supporting facilities for the National Institutes of Health.

The appropriation request of $8,000,000 in fiscal year 1987 is for the following:

Animal Facilities Project: With increased public interest in the use and care of animals in research, NIH administration is concerned that its own facilities for housing and utilizing animals meet its own guidelines on animal use and care, as well as others that will be promulgated as the result of recently enacted legislation. Approximately 80 percent of NIH intramural animal holding space meets the standards of the American Association for Accreditation of Laboratory Animal Care, leaving 83,000 square feet of unaccredited space.

The NIH has established a goal of insuring that all animal facilities on the NIH campus meet the AAALAC standards by October 1987. Two phases of activities in this effort have been identified. The first phase, of two-year duration, would involve the consolidation of existing animal facilities within individual buildings, renovation of existing space, and new construction; the second phase, of 5 to 10 years, would require the greater consolidation of scattered animal holding activities and construction of new facilities. The 1987 request for $3,000,000 will permit progress under the first phase of this plan by allowing the consolidation of some of the existing animal facilities, renovation, and construction.

Repairs and Improvements: The Repairs and Improvements program applies to the main physical plant at Bethesda, Maryland and other field stations for which NIH is responsible. Activities supported with these funds are relatively small and unanticipated to the extent that lead time is not sufficient to request funds during the regular budget cycle. The request of $5,000,000 in FY 1987 will provide for the maintenance of our extensive physical plants and for changes related to program needs.

Thank you. I shall be happy to respond to any questions you may have.

Biography of Edward E. Nicholas, Jr.

October 20, 1923. Rock Island, Illinois.
Married, three children.

Education. A.B., Augustana College, 1949. M.S., Columbia University, 1950.

Professional History. 1950-1951, Salary & Wage Analyst, Rock Island Arsenal, Rock Island, Illinois. 1951-1952, Salary & Wage Chief and Assistant Personnel Officer, Pittsburgh Ordnance District, Pittsburgh, Pennsylvania. 1952-1955, Assistant Salary & Wage Chief, Ordnance Corps, Pentagon. 1955-1958, Salary & Wage Chief, Ordnance Corps, Pentagon. 1958-1962, Chief, Civilian Personnel Management Section, Ordnance Corps, Pentagon. 1962-1963, Personnel Management Specialist, NIH. 1963-1969, Chief, Personnel Staffing Branch, Office of Personnel Management, NIH. 1969-1974, Assistant Director for Operations, Office of Personnel Management, NIH. 1974-Present, Director, Division of Personnel Management, NIH. 1979-1980, Acting Associate Director for Administration, NIH. February 1986-Present, Acting Associate Director for Administration, NIH

Military Service. 1943-1946, United State Army, Office of Strategic Services.

Honors, Awards. Sustained Superior Performance Award, 1973. Superior Service Award, 1974. Public Health Service Special Recognition Award, 1981.

Statement of Storm Whaley

The Office of Communications at NIH has responsibility for coordinating the public information activities of the several components of the NIH, as well as for providing guidance and technical assistance to assure that the NIH maintains effective communication with the members of the nation's health professions and the scientific community.

NIH public information personnel devote a major portion of their time to preparing and disseminating research-derived informational materials on specific disease problems and measures for their prevention or treatment. In recent years, components of the NIH have received more than 800 thousand telephone or mailed inquiries annually from members of the general public. The materials developed by our information offices are essential to meeting the public's requests. Public service announcements for radio and television are produced and distributed nationwide to inform the public of the availability of the approximately 700 different informational brochures and leaflets on specific health matters.

In all these activities we are providing information from rather than about the National Institutes of Health.

Celebration of the agency's Centennial, however, provides an appropriate occasion and opportunity for informing the American people more fully about the NIH, the agency that Lewis Thomas has called "not only the largest institution for biomedical science on earth," but also "one of this nation's great treasures."

The principal item on our celebration agenda is the production of a series of one-hour television specials.These extensively researched programs will tell the story of advances in the biological sciences and medicine in this country over the past century and will be designed for initial presentation on the Public Broadcasting Service. They will be organized so as to link historical development with the advances involving NIH in new understanding of biology and clinical practice for which our research was directly or indirectly responsible. The purpose is to provide audiences with a clear understanding of the process and purpose of basic biological research. Our plans for the series include followup programs where the local station would spend an additional 30 minutes following each broadcast for call-ins

and review of the local angles of the just-completed documentary. In many instances such followup programs would feature NIH-funded researchers.

A series of sixty-second public service messages called "NIH Historical Minutes" is projected to be created from materials and footage from the documentaries. These messages would lend themselves either for use on commercial or public television. For example, a sponsor might make the "minutes" part of a major promotion on the commercial networks. Models for this approach were first used during the national bicentennial. More recently, this device has been used in connection with the Statue of Liberty Centennial.

The research done for the documentary series will produce materials easily adaptable for publication of a major centennial book for the general public. The book and the television series can be developed as parallel efforts and cross-promoted.

The television series and associated projects are the principal objects of a fund raising effort by the NIH Centennial Committee. The Commitee is chaired by former NIH Director, Dr. Donald S. Fredrickson, who is now President of the Howard Hughes Medical Institute. Most of the members of the Committee are "alumni" of our intramural research program.

Other financial needs include the cost of transporting and displaying a traveling exhibit on the NIH and biomedical research to at least 12 major science museums and learning centers throughout the country. We have arranged with the Smithsonian Institution for a Centennial exhibit in the so-called "Case of the Month", a prominent display on the main exhibit floor on the National Museum of American History. We hope to arrange for a year-long display in the Hall of Medicine.

The microscope used by NIH's first Director, Dr. Joseph Kinyoun, will be loaned by the Smithsonian for display at the NIH Visitor Information Center.

The Centennial provides an appropriate "news peg" for feature articles in newspapers, magazines, radio and television networks and stations. Major magazines and other national media are showing interest in Centennial related articles, and we will produce feature materials in a variety of formats on many subjects of medical progress, built around themes contrasting "then and now." The first such Centennial related material of significant length is expected to appear in the May 1986 issue of Ladies Home Journal.

In October 1987 the NIH will hold a public open house on the Bethesda campus with a large number of exhibits and a continuous series of lay-oriented presentations on health questions. The last NIH open house, held as a bicentennial event, attracted some forty thousand visitors over one weekend.

Another major set of activities for the NIH Centennial year at different locations throughout the nation is now in development.We have been in touch with the heads of research institutions in Boston, Atlanta, St. Louis, and San Francisco regarding regional celebrations of the NIH Centennial. We expect that centers in at least six additional cities will sponsor such events. Each celebration will be planned by the local sponsors and held at a different time during the year, but we are encouraging the organizers to emphasize involvement of the general public and involve the local affiliates of voluntary health organizations. In any case, we expect that such events will attract considerable regional media coverage and provide a setting for better informing the public about the importance of biomedical research.

A multi-image visual presentation on the history of NIH is being developed particularly for use at plenary sessions during annual meetings of major voluntary health organizations.

Copy is now in hand for a Centennial Edition of NIH Research Advances. This publication, last issued about ten years ago contains a substantial amount of background and current information on research conducted by the NIH. Although not highly technical, Research Advances is designed primarily as a medium for interesting bright young people in pursuing careers in research.

A number of professional and scientific societies plan salutes to the NIH during the anniversary year. International recognition also is expected. The European Medical Research Council (EMRC) scheduled its annual meeting for June 1987 in Washington to honor the NIH Centennial, and an internationl science symposium will be held here in connection with the EMRC meeting.

The Pasteur Institute will also observe its centennial during 1987, and with the NIH will hold a joint symposium on molecular biology in celebration of the 100th birthdays of both institutions.

We are in the process of developing plans for suitable recognition of the Nobel Laureates who either worked at or were supported by the NIH before receiving the prize. Fifty-five of the 82 American Nobel Laureates in Medicine or physiology or chemistry had such prior association with NIH .

A substantial number of today's leaders in academia, science, and industry are "alumni" of NIH, having served at Bethesda as research trainees, scientists or program leaders over the past 40 years. Alumni reunion week will be held at NIH in October 1987, and the alumni will participate in an extensive program of seminars, laboratory reunions, etc.

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Thus far we have not been successful in receiving approval for a Centennial postage stamp. In response to our proposals we have been advised that, because biomedical research was the subject of a stamp about two years ago, another such issuance now is not timely. The earlier stamp, however, made no reference to NIH.

The NIH views the Centennial as more than an institutional birthday. It provides an occasion for creating a better understanding among the American people of the importance of biomedical research and an opportunity to convey a sense of its accomplishments and promise.

BUDGET REQUEST

Mr. NICHOLAS. All right, Mr. Chairman. I have with me, Dr. Becker, Associate Director for Research Services. I have submitted my statement for the record.

Just very briefly, my testimony covers two appropriations that support all NIH programs. First, the appropriation for the Office of the Director, that includes the Director and his staff who assist him in the administration and coordination of NIH programs.

The appropriation request for fiscal year 1987 for the Office of the Director is $36.7 million. This includes $10 million for the continuation of a program that supports biomedical research in small and minority schools and universities.

The second appropriation, for which Dr. Becker and I are testifying, is buildings and facilities. This appropriation provides funds for the design, construction, repair, and improvement of NIH facilities. The major items of our request under this appropriation are $3 million for renovation and construction of our animal holding facilities and $5 million for our ongoing program of routine repairs and improvements.

I will be glad to answer any questions.

Senator WEICKER. Didn't we take over buildings and property just a few years back from the convent?

Dr. WYNGAARDEN. Yes.

Senator WEICKER. Where do we sit on that?

Dr. WYNGAARDEN. The Congress appropriated the purchase price for the building, and we acquired it. We have since then entered into an agreement with the Howard Hughes Medical Institute to use that property as a base for the training of medical students during an elective year in research at the National Institutes of Health.

The Howard Hughes Medical Institute is financing the program, and also the renovations of the building, to include some laboratories and a new wing for housing the students while they are with us for 1 year. The institute is putting about $10 to $11 million into the construction and building costs.

Our only expense connected with this program is the research expense and the laboratories. The Howard Hughes students who are selected, incidentally, in nationwide competition by a joint committee of NIH scientists and Howard Hughes people, work in the laboratories of some of our leading scientists.

This activity has had a marvelous start in its first year. Several of these students have requested an opportunity to stay a second year. We are in the process right now of selecting the group to come in for the second year. Construction should be finished probably within the year, and the group will be housed on the campus. We think that we have put that property to good use.

Senator WEICKER. The Howard Hughes Medical Institute, is this a foundation, is it a for-profit group, or what is the nature of the Howard Hughes Medical Institute?

Dr. WYNGAARDEN. In 1953, Mr. Hughes created the Howard Hughes Medical Institute, and gave it ownership of the Hughes Aircraft Co., in Burbank, CA. That was never threatened by the dispute over the will. The will concerned his other holdings. The only thing that might have happened to the institute, had a will been found, is that additional resources might have been given.

In its early days, the institute was fairly small—supporting individual scientists in a limited number of schools. As the resources increased, the institute was reorganized about 10 years ago, and began supporting major programs in different schools.

In the legal sense, it is an operating institute. They are fond of saying, "We are a 13-story institute. The only difference between us and the usual is that each of our 13 stories is in a different city." They do not make grants and are not a foundation. That is important because a scientist cannot apply for support to the Howard Hughes Institute. They select people and hire them as full-time employees of the Howard Hughes Medical Institute.

Senator WEICKER. What are the legal ramifications of that, should that individual come up with some discovery?

Dr. WYNGAARDEN. They have a patent policy, though I do not know just what the specifics are. It interdigitates with ours because Howard Hughes may provide the scientists with base support, not only salary, but also the laboratory, equipment, supplies, and rent at the schools. There is a substantial amount of research support. That same scientist can apply to NIH for additional support for additional projects. If we have any money in the project, we also have patent rights on the results, if appropriate.

Senator WEICKER. Again, I don't want to presume anything, but this is a learning process. If I were the president of my own family's business, Squibb, I would love to have some buildings and personnel on the campus of the National Institutes of Health, but I don't understand how the public moneys that are represented by the National Institutes of Health can be put at the disposal of any private entity. I have never heard of that. When did this business start?

Dr. WYNGAARDEN. It has been in existence for a little more than 1 year. We had a major dedication of the building. We had the inauguration of this program during the past year. Secretary Heckler spoke and Mr. Natcher was there. I think that your calendar did not permit your attending.

Senator WEICKER. My concern is that the work product, if you will, that emanates from this facility, there could be a conflict, rather than belonging to the people of the United States, it can belong to the Howard Hughes Medical Institute. How do you respond to that?

Dr. WYNGAARDEN. I understand your question. The research that is conducted here is for the training of the medical students. What I mentioned about the institute has nothing to do with the NIH. All the rest of the Howard Hughes Medical Institute is entirely outside of our control. We only interact in the sense that some of their scientists also apply to us for support, just as they do from Salk, Rockefeller, and the others.

The only part that is a joint venture is the training of 25 to 30 medical students a year in research at the National Institutes of Health. We look on it as a marvelous public/private sector example of how outside money and Government money can address synergistically an important problem.

Senator WEICKER. I don't argue that. The only point that I argue would be, as I said, if something emanates from this effort, are you guaranteeing this committee, in other words, that that does not become the property of the Howard Hughes Medical Institute.

Dr. WYNGAARDEN. That is quite true. This work is done at the National Institutes of Health, and it has the same status as any other intramural research done at the NIH.

Senator WEICKER. As part of this, they have gone ahead and refurbished some of these buildings?

Dr. WYNGAARDEN. Yes.

Senator WEICKER. Was the refurbishment in tune with your master plan? If tomorrow Hughes disappeared from the scene, in other words——

Dr. WYNGAARDEN. Then it is ours.

Senator WEICKER. Would it fit in with your present physical plant?

Dr. WYNGAARDEN. Yes; we have excellent use for that building, there is no question about that.

Senator WEICKER. I gather you aren't doing much from this breakdown of the budget that I heard, aside from maintenance. There is not much plan as far as building or refurbishing on the campus, is there?

Dr. WYNGAARDEN. Dr. Becker can speak to that.

Dr. BECKER. One of the items that is in the request is renovation of our animal facilities, which are of considerable concern to us. We are not planning any new construction beyond the animal area, except for an expansion of the surgery area in the Clinical Center. There is a letter on its way to you explaining that we plan to reallocate the $7 million this year that has been appropriated for Clinical Center modernization

for the replacement of antiquated facilities for heart and neurosurgery. This will involve a modest amount of new construction and renovation of existing space.

Senator WEICKER. Jim, do you consider all of your research and hospital facilities, as compared to dormitories, to be in topnotch shape now?

I gather not, when it comes to the surgical facilities, et cetera, I gather that needs modernization. What about other areas?

Dr. WYNGAARDEN. We have campus facilities that vary in age. The Cancer Institute building dates back to 1937, the Clinical Center from 1952 or 1953. Many of the older buildings are in need of renovation and we have a plan for renovation of laboratory buildings that is ongoing right now.

Some of the laboratories are not in topnotch shape, and others are in excellent shape. The animal facilities are a special case because, as you know, we have had a great deal of pressure from the extramural community on the care and use of laboratory animals and have guidelines for animal care that we are insisting grantee institutions meet. We feel that we ought to be meeting them ourselves, and have an accelerated program underway that we hope will result in total accreditation of all our facilities within 2 years.

Senator WEICKER. Senator Proxmire.

Senator PROXMIRE. Director Nicholas, the General Accounting Office came out with a report this month indicating that NIH has not fully complied with four of eight Equal Employment Opportunity Commission requirements for affirmative action since the NIH plan was approved in February 1983.

What is your timetable for implementing this plan? First, when do you plan to establish numerical hiring goals for underrepresented groups?

Mr. NICHOLAS. We have such goals established already. We are not satisfied with the way in which they must be implemented, by that I mean, the cells are too small to provide meaningful goals. We are studying an expansion of the categorization to correct this.

Senator PROXMIRE. Let me ask Mr. van der Voort to follow up on that.

Mr. VAN DER VOORT. When do you think you will have the new set of goals?

Mr. NICHOLAS. In about 60 days.

Senator PROXMIRE. When do you propose to have in place minority and women's recruitment plans for all of your organizational components?

Mr. NICHOLAS. The recruitment plans for the service fellows should be in place at about that same time; this is the one that we are concentrating on.

Senator PROXMIRE. How about the other components?

Mr. NICHOLAS. Probably in another 60 days beyond that.

Senator PROXMIRE. When do you plan to complete an analysis to identify barriers to achieving full representation of minorities and women?

Mr. NICHOLAS. Our analysis is on schedule, and the ones that were discussed have been completed already.

Senator PROXMIRE. I understand that you will have 12,649 people at NIH. One finding of the General Accounting Office was that as of December 1984, minorities and women were underrepresented in 63 of 108 race, ethnic origin, gender, occupation, and grade level categories. How could that happen?

Mr. NICHOLAS. The representation of minorities depends very closely on the pool of qualified people from which those people must be selected. We are dealing in part with a sociological phenomenon in that the higher education institutions are just beginning to catch up and provide us with a supply of qualified people, particularly at the doctoral level.

Senator PROXMIRE. You don't seem to have a very good record. You say that it is primarily because of the lack of qualified women and qualified minorities.

Mr. NICHOLAS. Yes, sir; I might add that in occupation for which preparation at the bachelor's degree level, is appropriate, the biologists, for example, minorities, including blacks, are overrepresented in comparison with the appropriate population. When you move to the doctor level, it becomes more of a problem.

Senator PROXMIRE. You are satisfied, however, that under the present circumstances, you will be able to meet the goals that have been set, and that you will be able to have a far greater number of areas where you do have representation of women and minorities?

Mr. NICHOLAS. As long as we compare our progress with the available qualified applicants, yes.

Senator PROXMIRE. Thank you, Mr. Chairman.

Senator WEICKER. Thank you, Senator Proxmire.

Now maybe you would like to tell Senator Proxmire and myself exactly what is involved vis-a-vis the centennial plans.

Dr. WYNGAARDEN. Yes, sir; Mr. Storm Whaley who is the Associate Director for Communications has a prepared statement that will address this matter.

Mr. WHALEY. I have provided a statement, Mr. Chairman, but if you have any questions, I would be glad to answer them.

The NIH does provide a lot of information in the normal course of events. We get about 800,000 inquiries each year, and we publish a great deal of material to respond to them. However, most of the output from NIH is information that is provided from our activities, rather than information about NIH.

We think that the centennial will provide us with an opportunity, perhaps even a responsibility, to talk to the American people about this agency that serves in so many different ways. We look at the centennial as that kind of opportunity, occasion, and responsibility.

The centerpiece of our centennial activities is a series of 1-hour television programs for broadcast, probably, on the Public Broadcasting Service. We visualize as many as five or six of them in a series in the fall of 1987. These would tell the story of biomedical research over the past century, or what we call in our slogan, "A Century of Science for Health."

From this, we would also, of course, trace the history of the NIH as a participant in these developments in biomedical research over this century.

The films would also be used subsequent to their broadcast in many different ways, for example, in school settings and so forth. As a derivative of the production of the documentary, we would also produce 1 minute announcements, called "Centennial Minutes," for use both on PBS and on commercial television. As you know, the national bicentennial used this device very effectively. They prepared 1 minute announcements to be sponsored by commercial interests in a so-called wraparound format. The same thing has been done most recently on the Statue of Liberty.

Another planned derivative of the film is a book about the progress in biomedical research through the years since 1887. The same research that makes it possible for us to do the documentary, will make this project possible also. The photography would also lend itself to illustrating such a volume, and the book can be jointly promoted with the centennial film itself.

Another activity that we plan to do is to reach out to the communities throughout the United States with exhibits. We plan to have an exhibit called "the Case of the Month," appear in the Museum of American History on The Mall, telling about the history of NIH.

We hope to have a year-long exhibit in the Hall of Medicine in the same museum. At the same time, we will take advantage of the Smithsonian Institute's Traveling Exhibit Service, and travel with more modest exhibits around the country to at least 12 centers during the centennial year. This, again, is to expose larger numbers of people to what we are doing at NIH.

We also plan to have regional salutes, or regional celebrations of the NIH birth, centered in about 10 centers of research, for example, in Boston, San Francisco, St. Louis, and in other places. The local institution and the people who have been active in research in the local institutions would have a celebration which we believe will generate substantial amounts of local publicity. It is our purpose to involve people from the NIH itself in these celebrations through presentations and appearances, as well as to invite the congressional representatives of those areas to participate, if they wish to do so, in a local celebration of biomedical research; because our research activity has been essentially a partnership with local institutions, particularly since World War II.

Senator WEICKER. Let me ask you, when is the centennial, which year?

Mr. WHALEY. The centennial is in 1987. The actual founding date is in August 1887, but our activities will be beginning this fall, and will culminate in the fall 1987 with the production.

Senator WEICKER. How much do you estimate the cost to be for these types of activities?

Mr. WHALEY. We are asking the private sector for about $3 million to fund these activities. A funding committee has been formed. Dr. Donald Fredrickson, the head of the Howard Hughes Medical Institute, is the chairman of this group. He has a prominent group of people, alumni of NIH, who are serving on this committee.

Senator WEICKER. I don't see that there is any purpose to be served by going over in some detail at the present time, except to say that I think you want to make sure that the message gets out there as to what it is that you are all about.

The problem is that the President is unwilling to do it, and I don't command that large a constituency politically, and you don't scientifically. I think until the American people realize what a jewel they have here, we are not going to get the money which I think you deserve to have.

I would say, in the course of the weeks ahead, I would like to sit down and go over this in a little more detail. I am delighted, very pleased, and appreciative of any efforts that are coming forth from the private sector, but I think also that we have to be prepared to do our own thing in that fashion.

Dr. WYNGAARDEN. There is a component of the centennial plan that involves a scientific symposium, and we will have some NIH funds in that.

Senator WEICKER. I am not worried about the scientific community. This is that one window of time in which the American people, the ones that ought to really be the beneficiaries of all these billions of dollars, which I believe in, and which I would, in fact, double if I had my way. These are going to the scientists, and they are well aware, I hope they are well aware.

Dr. WYNGAARDEN. Yes; they are.

Senator WEICKER. This is that moment in time when we have to somehow present it in a fashion where it is understood and appreciated by the people who are footing the bill. I just want to make certain that we do a good job on that score.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Thank you. There will be some additional questions from myself and other Senators which will be submitted for your response.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

MINORITY RESEARCH PROGRAM

Question. What is the status of the Minority Research Program that is managed in the Office of the Director?

Answer. The Research Centers in Minority Institutions (RCMI) Program was developed in 1985 to establish research centers in those predominantly minority institutions which offer doctoral degrees in the health professions or the sciences related to health. Of the 16 eligible institutions, all submitted RCMI applications, which were peer-reviewed; and all 16 were recommended for approval. Seven initial awards for the RCMI program were made September 30, 1985, obligating $4.77 million. These selections were based on recommendations by the Division of Research Resources National Advisory Council.

Question. How is the program working thus far?

Answer. RCMI grants significantly enhance the capacity of the predominantly minority institutions for the conduct of biomedical and/or behavioral research by strengthening and augmenting both their human and physical resources. Some examples of how the Program is working follow. Major renovations, equipment acquisition, development of core laboratories, a central office for grants and contracts, and faculty recruitment efforts that are supported by the RCMI Program are well underway. At one of the grantee institutions, the recruitment of five neuroscientists is in the final stages. Major renovations of the animal facilities and an electron microscope suite have been completed. This institution has also reorganized its grants and contracts office in order to provide assistance to its entire research faculty.

Question How many institutions are being funded by this program?

Answer. Seven institutions are currently being funded through the RCMI Program. They include a college of pharmacy, three medical schools, and three graduate schools. The grants were awarded to: Florida A&M University, Tallahassee, Florida; Meharry Medical College, Nashville, Tennessee; Atlanta University, Atlanta, Georgia; Howard University, Washington, D.C.; Hunter College, New York City, New York; College of New York, New York, New York; and Ponce School of Medicine, Ponce, Puerto Rico.

Question. In your professional judgment, how many more institutions should be funded to make a real impact on the problems of minority institutions to compete for research-oriented faculty and for research grants?

Answer. Seven of the 16 eligible institutions (44 percent) are currently funded through the RCMI Program. These seven institutions competed successfully within the NIH peer review system. The remaining 9 submitted applications whose quality ranged from very good to approvable but seriously flawed. If they continue their current efforts to develop and extend their research capabilities, their prospects for success in future national competitions should improve.

OFF-CAMPUS LEASING

Question. Dr. Becker, we see that your budget proposal again contains a request for a significant amount of money for leasing off-campus office facilities through the General Services Administration. The Congress gave GSA the authority to enter into lease-purchase arrangements for construction on Government land. Couldn't this authority be used to build an office building on the NIH campus and end this perpetual drain on money for rent?

Answer. Over 2,600 scientist-administrators and support staff who manage most of NIH's extramural programs are currently housed in leased office space in four locations in Bethesda and Silver Spring. The lease-purchase authority now held by the General Services Administration (GSA) permits a private developer to construct a building on Government-owned land (such as the NIH campus) and lease the building to the Government, with title passing to the Government after a specified period, not to exceed 30 years. NIH has been exploring the use of the lease-purchase authority with the GSA and will continue to pursue the option through DHHS and OMB channels.

AIDS

Question. Dr. Wyngaarden, the FY 1986 appropriation for the National Institutes of Health placed $70 million in the Office of the Director specifically for research on AIDS. Please describe how the distribution decisions were arrived at.

Answer. The amounts available within the appropriation of the Office of the Director now total $53,075,000. The original $70 million has been reduced by sequestration and the proposed rescission.

Question. How long would it normally take between an Institute request and release of the money?

Answer. The uncertainties associated with the changes in the FY 1986 budget, the proposed rescission, and the sequestration precluded early action on the Institute requests. In more normal circumstances, we anticipate that the amount of time required from request to release would be less than a month.

Question. In your professional judgment, was placing 1/2 of NIH AIDS research money in the Director's Office an efficient method of distribution?

Answer. It is my professional judgment that the concept of placing a portion of AIDs funding in the OD appropriation is an excellent approach to meeting the needs of the NIH program. The availability of an undistributed "pool" of resources permits much-needed flexibility in responding to emerging opportunities.

BUILDINGS AND FACILITIES

Question. In the FY 1987 budget, the total for Buildings and Facilities comes to $8,000,000; this compares with $21,730,000 for FY 1985. How will this dramatic decrease be achieved? How will

this budget affect the continued renovation of the older buildings on campus?

Answer. The 1985 appropriation included funds for the Clinical Center modernization, renovation of laboratory buildings, design of a Child Health Building and routine repairs and improvements. The 1987 request seeks funds for only the upgrading of animal facilities and for routine maintenance.

A total of $3,000,000 is included in the 1987 request for initiation of a program for upgrading animal facilities on the NIH campus to meet AAALAC accreditation standards. No new funds are requested for the Clinical Center modernization project in 1987 since a proposed reprogramming will result in a new surgical facility and a greater consolidation of animal housing.

Regarding the continued renovation of laboratory buildings, funds were not requested in the FY 1987 budget for this project because they cannot be utilized in 1987. Renovation of Building 5 cannot begin until its occupants are able to be relocated to a renovated Building 4. Request for funding will resume in 1988 to support the next scheduled phase of the project.

SPACE AND EQUIPMENT NEEDS

Question. Have space and equipment needs for NIH been studied, and plans made (with other agencies, the private sector, and academe) to meet the needs of the future?

Answer. Space and equipment needs for the intramural programs of the NIH have been studied. A comprehensive effort to address space needs several years ago resulted in the initiation of a construction project to upgrade and renovate NIH laboratory buildings, a project now in its sixth year. More recently, space needs have been reassessed in light of the NIH plan to meet AAALAC accreditation standards for its animal holding facilities by October, 1987. The committee spearheading this effort is reviewing the use of existing space and has proposed a plan involving program consolidation and building renovation and construction. Some aspects of this program can be accomplished immediately while others can be completed only over the next five to ten years. The space needs of the entire NIH community underlie the development of the NIH Master Plan, the major planning document for all construction, renovation and maintenance of the NIH.

Regarding the research instrumentation needs of the extramural environment, a report was provided recently to the House Appropriations Committee on the proceedings of the December 1985 meeting of the NIH Director's Advisory Committee, a session that addressed the problem of obsolete biomedical research instrumentation. The committee concluded that an erosion of instrumentation has occurred over the last ten years, particularly affecting small instruments, and that the existing NIH support mechanisms should be funded to the extent possible.

In addition to the Committee's proceedings on this issue, the NIH supported, in conjunction with the National Science Foundation, a survey of selected U.S. biological science departments and facilities to identify existing instrumentation needs. A report of

the survey's findings was issued, dated April 1985, and is available for review.

ACCESSIBLE BUILDINGS

Question. Have barriers to the handicapped been removed from NIH buildings and facilities? What provisions exist to insure that new or remodeled buildings and facilities will be accessible to the handicapped?

Answer. Construction projects to remove handicapped barriers in areas of high public use and/or known handicapped population were awarded in January 1986 with scheduled completion in November 1986. Continuation of the handicapped construction program to cover such areas as additional restrooms, elevator controls, door openings, and fire alarms is being developed by the NIH Handicapped Committee, with additional funding being required in future years. All designs for new and renovated facilities require provisions for the handicapped.

Question. What sorts of energy conservation measures will be used to help reduce NIH's energy costs? What sorts of studies will be conducted to insure that energy is not conserved at the expense of healthful working conditions?

Answer. A number of options exist to reduce NIH's energy costs. These options are categorized generally as those achievable through low or no cost and those achievable through moderate investment. Both types are continually reevaluated in light of changes in program requirements, condition of the plant, and capabilities of the utility systems. Conservation measures of the first type include: the reduced operation of heating, ventilating, and air-conditioning (HVAC) systems in office and non-research areas at night and on weekends; the reduction of lighting levels in such areas to minimum acceptable standards; and the recalibration of HVAC systems to meet minimum acceptable comfort and operational standards. Application of such measures to research facilities is more difficult because of health and safety considerations in laboratories and environmental standards required in animal holding areas. Such actions are not taken without the consultation of involved scientists, engineers, and health safety experts.

Options of the first type and those involving investment are being evaluated and integrated into the NIH Master Plan. Energy conservation measures are implemented during renovation, upgrades, or construction of facilities.

Question. Are there plans to rent, lease, or sell older equipment (often less efficient, costlier to repair, and more prone to breakdown than newer equipment) to private sector users, academe, or other agencies? Do you have any plans to rent, lease, or sell unneeded equipment to private sector users, academe or other agencies?

Answer. Equipment that is no longer required by an NIH laboratory is sent to a central NIH property office where it is placed at the disposal of other NIH components. If not acquired by another component, the equipment is declared excess. The NIH policy on the use of excess equipment follows GSA guidelines. Equipment

that is declared excess, unless requisitioned by another institute or DHHS component, is made available through GSA, in descending order of priority, to other U.S. Government agencies, State governments, U.S. schools and universities, and nonprofit organizations. Equipment that cannot be disposed of in this fashion is sold by GSA as Government surplus or as scrap.

Question. Because of reductions in staff, work, or other reasons, will there be unused NIH buildings and facilities in FY 1987?

Answer. Although there has been an overall reduction in FTE usage, the reduction has not been significant. Not affected by FTE ceilings are the staffing components of visiting fellows, contract personnel, guest workers, and student aids who require laboratory and office space in order to contribute to the NIH mission.

IMPACT OF BUDGET REDUCTION

Question. The President's Budget Proposal for FY 1987 reduces your budget by $10,291,000 for OD and $6,900,000 for Buildings and Facilities under FY 1986 appropriated levels. Gramm-Rudman-Hollings, if triggered, could reduce your budget even further maybe by as much as 20 percent. I've known this would reduce a number of grants, possibly the size of grants, Centers, training, etc., etc. Can you give us some idea of the impact of these reductions on the kinds of research that would be stopped or lost? What impact might this have on the health of our citizens five and ten years down the road? Can you discuss your contingency plans if these massive budget cuts should come to pass?

The Office of the Director (OD) at this time does not have a specific contingency plan for further sequestration below the amounts currently requested in the FY 1987 President's Budget.

It is difficult to predict what effect would be on the Nation's health in future years. However, a reduction of 20 percent would reduce the level of biomedical research supported by the NIH, which impacts directly on new health diagnoses, preventions and treatments.

ANIMALS IN RESEARCH

Question. The use of animals in research has been and, I believe, will continue to be a topic of concern and discussion. Please review for us NIH activities in this area including the University of Pennsylvania and Columbia problems.

Answer. NIH activities relating to the care and use of research animals, during the last several years, include the following:

(1) Revision of the Public Health Service (PHS) Animal Welfare Policy that requires all awardee institutions to submit to NIH an Animal Welfare Assurance, describing an acceptable program for laboratory animals and committing the institution to compliance with the PHS Policy; the NIH Guide for the Care and Use of Laboratory Animals; the Animal Welfare Act; and all other applicable laws and regulations. The revised policy is substantially stronger than the

1979 policy, and requires an expanded Institutional Animal Care and Use Committee with responsibility for protocol review.

(2) A series of site visits to assess the adequacy of the assurance system. Many of the specific policy revisions were a result of recommendations arising from these site visits. The random site visits will continue through 1988.

(3) A series of regional educational workshops to assist awardee institutions in understanding their responsibilities and implementing a successful program of laboratory animal care and use.

(4) Investigations, when necessary, into alleged violations of the PHS Animal Welfare Policy. The University of Pennsylvania and Columbia University are two examples of such investigations, and are briefly summarized below:

University of Pennsylvania - Following findings that research conducted in the Head Injury Laboratory of the University of Pennsylvania failed to meet the standards of the NIH Guide, research in that laboratory was suspended, and new awards were not made to the University pending review of the institution's new Animal Welfare Assurance, required by the revised PHS Policy to be submitted to NIH by January 1, 1986. In March of this year NIH completed a substantive review of the assurance which included a site visit, and found it to be provisionally acceptable and sufficient to meet awardee institution assurance requirements. Accordingly, the temporary restraints on selested new commitments of funds have been removed.

Columbia University - Following an unannounced site visit to the Health Sciences Division of Columbia University (HSDCU), NIH suspended all funds for research involving vertebrate animals, with the exception of research involving only rodents. The on-site evaluation revealed serious deficiencies that constituted a material failure to comply with the PHS Policy. Funding restrictions will be lifted only after the deficiencies have been corrected and NIH has approved the HSDCU's Animal Welfare Assurance.

Question. In your professional judgment, is the Federal Government spending enough in this area, including site visiting of facilities that use animals, to answer the concerns of our citizens and meet the needs of our research scientists?

Answer. The Federal government is spending a considerable amount of effort and money in enforcing its policies governing animals in research, and in assuring the public that their concerns are being addressed. The revised policy, the educational program, site visits and investigations are all ways that the government is dealing with the issue of animals in research.

IMPACT OF BUDGET REDUCTIONS

Question. If the automatic provisions of Gramm-Rudman-Hollings are triggered in FY 1987, your Institute may well have its budget reduced by 20-25%. Have you prepared a contingency plan in the event Gramm-Rudman-Hollings becomes reality? If so, please send a copy of your plans to this Committee. If cuts of this magnitude become reality, how will they be distributed:

1. Intramural vs. extramural programs;
2. Peer review system; Would number of site visits be reduced? Would travel to NIH to study section meetings be affected?
3. Would NIH employees have to be furloughed?
4. What major programs would have to be cut back?

Please list the research programs of the highest priority that should not be cut and why.

The Office of the Director (OD) has not at this time developed a plan to further reduce its budget as a result of additional sequestering in FY 1987. The President's Budget was devised within the provisions of the Gramm-Rudman-Hollings Act, which would preclude the need for sequestrations in FY 1987.

SUBCOMMITTEE RECESS

I have to meet with the Leader. The subcommittee will stand in recess until tomorrow when we will continue our hearings on the budget requests for the Department of Health and Human Services, with testimony from the Health Resources and Services Administration, and the Office of the Assistant Secretary for Health.

Immediately upon the conclusion of that testimony, we will then pick up on the various institutes of the National Institutes of Health which were scheduled to be heard yesterday, and that, I believe, will conclude our business.

I might add, if at tomorrow's hearings there are any other matters that have occurred, or that need further explanation, please feel free, Jim, to do so before those hearings are over. I am quite prepared to go right through lunchtime, if need be, and do whatever is necessary in that regard.

Thank you all very much.

Dr. WYNGAARDEN. Thank you, Senator.

Senator WEICKER. The subcommittee stands in recess.

[Whereupon, at 11:52 a.m., Tuesday, March 11, the subcommittee was recessed, to reconvene at 9:30 a.m., Wednesday, March 12.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1987

WEDNESDAY, MARCH 12, 1986

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:30 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker, Proxmire, Harkin, and Specter.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH RESOURCES AND SERVICES ADMINISTRATION

STATEMENT OF JOHN H. KELSO, ACTING ADMINISTRATOR

ACCOMPANIED BY:

DR. EDWARD D. MARTIN, ACTING DEPUTY ADMINISTRATOR
JAMES A. WALSH, ASSOCIATE ADMINISTRATOR FOR OPERATIONS AND MANAGEMENT

OPENING REMARKS

Senator WEICKER. Today, we will hear first from the Health Resources and Services Administration [HRSA] which has jurisdiction over the maternal and child health block grant, community health centers, and a variety of programs delivering health care services to underserved groups, as well as health professions and nurse training programs.

In fiscal year 1986, Congress provided $1.5 billion for these programs. While the budget request for the agency for fiscal year 1987 totals $1.1 billion, all health professions and nurse training programs of any sort have been eliminated. In addition, the budget request includes a proposal to institute a block grant combining community health centers, black lung clinics, migrant health programs, and family planning at a reduced level of spending

After this, we will continue to the Office of the Assistant Secretary for Health, and here to testify for their request is Dr. Donald Macdonald, the Acting Assistant Secretary for Health. Dr. Macdonald has been

before the subcommittee in his former capacity as the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration.

Finally, following the Office of the Assistant Secretary for Health, we will conclude with the National Institutes of Health, rescheduling the hearings that we had to postpone from Monday, March 10.

Please proceed. Why don't you introduce your colleagues?

Mr. KELSO. Thank you, sir.

INTRODUCTION OF ASSOCIATES

On my right is Dr. Martin, who is the Acting Deputy Administrator of the agency. On my left is Mr. Walsh who is the Associate Administrator for Operations and Management. Behind me is Mr. Thomas Hatch, who is the Director of the Bureau of Health Professions; Dr. Vince Hutchins, who is the Acting Director of the Bureau of Health Care Delivery and Assistance; Dr. Daniel Whiteside who is the head of the Bureau of Health Maintenance Organizations and Resource Development; and Mr. Bill Beldon, representing the Office of the Secretary.

PREPARED STATEMENT

I will enter the statement for the record, if I may, and just briefly summarize it.

This budget that we are presenting to you is very similar to the budgets we have presented in the past few years. It reflects a set of very difficult choices that we have had to make among competing priorities. I think that this is the hallmark of the budget.

As you have indicated, it proposes a primary health care block grant, which would combine community health centers, migrant health, black lung, and family planning, and does eliminate the programs related to health professions and health planning.

We will be glad to try to answer your questions.

[The statement follows:]

STATEMENT OF JOHN H. KELSO

I appreciate this opportunity to appear before you today to discuss the fiscal year 1987 budget request for the Health Resources and Services Administration. As you are aware, Mr. Chairman, this budget excludes the Indian Health Service, which is reviewed by the Subcommittee on the Department of the Interior and Related Agencies.

The Health Resources and Services appropriation consists of health services, health professions and nurse education, medical facilities and health maintenance organization programs. The Administration will soon propose legislation to extend those authorizations for which funding is requested in the fiscal year 1987 budget.

The fiscal year 1987 budget request for Health Resources and Services is $1,182,670,000 and 2,489 full-time equivalent (FTE) employees. Included in this request are funds for: block grants to States to provide health services to mothers and children, the poor, migrants, black lung victims and other needy Americans; to continue the health care programs of the National Health Service Corps; to operate the Gillis W. Long Hansen's Disease Center; to provide a Federal payment to Hawaii for treatment of persons with Hansen's disease; to continue monitoring the medical facilities and health maintenance organization loan portfolios; and to manage the Health Education Assistance Loan program.

Health Care Delivery and Assistance

In 1987, $478,000,000 is requested for the Maternal and Child Health Block Grant, the same amount as was appropriated in 1985 and a 4.3 percent increase over the funds available in 1986. These funds will provide consolidated grants to each of 57 States and insular areas to provide a broad range of health services, including preventive care, primary care and rehabilitative services to mothers and children. Funds are allocated on a pro-rata percentage system. In addition, funds are provided for special projects of regional and national significance.

The Primary Care Block Grant is proposed to be expanded in 1987 to include community health centers, black lung clinics, migrant health centers, and family planning activities. The 1987 budget request provides $565,100,000 for grant awards to 50 States, the District of Columbia and Puerto Rico, and assumes the enactment of proposed new legislation. By combining categorical programs into the Primary Care Block Grant, this proposal will enable States to direct resources to the areas of greatest need while continuing to provide: primary care services; health services for respiratory and pulmonary impairments in coal miners; health services to migrant and seasonal farmworkers and their families; and family planning services to populations in need.

The 1987 budget request of $46,996,000 for the National Health Service Corps will support a total field strength of 3,292 physicians and other health professionals, including 571 federally salaried assignees. In addition to Federally salaried field assignees, 2,721 providers will be fulfilling their scholarship obligations as private practitioners, about the same number as in 1986. Through ongoing reliance on private placement with non-

Federal employers and the private practice option, this budget will support approximately the same total field strength while permitting a significant decrease in Federal funding. Under private placement assignments or the private practice option, a person may complete the service obligation -- incurred while receiving a National Health Service Corps scholarship -- through private practice in a health manpower shortage area. A private practice assignment requires no direct Federal salary support and thus provides needed service at less expense to the government.

In 1987, 990 scholarship obligors will be available for service for the first time. Of these, 50 are estimated to elect the private practice option and 727 will choose to serve in private placement settings. About 213 will become Federal employees -- 113 with the National Health Service Corps and 100 with the Indian Health Service.

The budget request includes $19,103,000 for the continuation of patient care, medical education and research activities at the Gillis W. Long Hansen's Disease Center, for Hansen's Disease contract patient care, and for payments to survivors and dependents of the Tuskegee Syphilis Study. Also requested is $750,000 for routine recurring repairs and improvements at the Gillis W. Long Hansen's Disease Center at Carville, Louisiana. Also requested is $2,500,000 for payments to the State of Hawaii to partially support the cost and treatment of persons with Hansen's disease; and $29,132,000 to manage and operate all programs of the Bureau of Health Care Delivery and Assistance. Beginning in 1986, total costs for the Federal Employee Occupational Health program, including consultation services, will be on a reimbursable basis. A total of 147 FTEs needed to carry out this function will be supported through the reimbursements. The total budget request for the Bureau's health service programs is $1,140,831,000 and 1,532 FTEs, excluding 147 reimbursable FTEs.

Health Professions

Federal efforts in support of health professions programs have provided a considerable investment during the last two decades in increasing the supply of health professionals (e.g., the number of physicians has increased by 197,700 or 61 percent since 1970; nurses have increased by 754,300 or 101 percent in the same period). They have contributed to improved specialty and geographic distribution of physicians, nurses, and other health professions, resulting in increased access and equity of services for rural and urban underserved populations. For example, there has been a decrease of 12 percent in the number of primary care health manpower shortage areas between June 1983 and December 1985 and a 25 percent decrease in the number of primary care physicians needed in these areas to bring them above the threshold for designation.

With the increasing supply of health professionals in the United States, the Federal government no longer needs to provide annual support. The Administration believes that the current and likely future supply of health professionals makes funding for health professions training programs a lesser budget priority. Federal support has built an infrastructure that should enable the institutions involved to continue these programs in the future.

In recognition of these trends, the Administration proposes discontinuation of health professions education subsidies in fiscal year 1987. The fiscal year 1987 request includes $3,401,000 and 72 FTEs for direct operations to administer the Health Education Assistance Loan program, the Student Loan Insurance Fund, the Health Professions and Nursing Student Loan revolving funds and for debt management and collection activities. The budget also requests authority to guarantee up to $100,000,000 in loans under the Health Education Assistance Loan program, which, combined with the cumulative Federal contributions to health professions and nursing student loan funds, will make $167 million available for student aid in 1987.

Proposed bill language to extend part of the Health Education Assistance Loan risk to lenders and to require borrowers to purchase credit life insurance, in concert with an increase in the loan insurance fee up to 8 percent, will assist in reducing the future potential drawdown on the Student Loan Insurance Fund resulting from increased defaults.

Health Maintenance Organizations and Resources Development

The budget request for the Health Maintenance Organizations and Resources Development for fiscal year 1987 is $15,628,000 and 243 FTEs. Some $10,000,000 of this amount will be obtained by the assessment of user fees for the qualification review process for Health Maintenance Organizations (HMOs), eligibility determinations of Competitive Medical Plans for the HCFA and to recipients of Hill-Burton loans and guarantees requesting modifications to existing loan agreements. No funds are requested for Health Planning programs, consistent with the Administration's long standing objection to the provision of Federal financial support for State and local health planning activities.

Direct operations funds will be used to: evaluate HMOs to determine whether they meet all requirements for Federal qualification; evaluate competitive medical plans to determine their eligibility to contract with the Health Care Financing Administration to provide care for Medicare beneficiaries; monitor qualified HMOs, including those with Federal loans and loan guarantees, to assure continued compliance with all Federal regulatory requirements; monitor approximately $1.0 billion in outstanding health facility loans and loan guarantees in order to minimize Federal default liability; ensuring that facilities which previously received Federal funding comply with requirements to provide a reasonable level of uncompensated care to persons unable to pay, estimated at about $500 million annually.

In addition, $20,000,000 is requested for the Medical Facilities Loan and Loan Guarantee Fund. The $20,000,000 requested in new budget authority, along with approximately $6 million in prior year unobligated funds and repayments of principal and interest, will be used to meet the total interest subsidy requirements of $26,000,000 in FY 1987.

Thank you for providing me with the opportunity to summarize the Health Resources and Services Administration budget for 1987.

Mr. Chairman and members of the Committee, my associates and I will be pleased to answer any questions you may have on the specifics of this budget request.

Biography of John H. Kelso

BIRTHPLACE : Iowa City, Iowa

DATE OF BIRTH: June 16, 1925

EDUCATION : State University of Iowa, B.A. 1949
State University of Iowa, M.A. 1950

PROFESSIONAL ACTIVITIES

1. September 1982 - Present*
Deputy Administrator
Health Resources and Services Administration
Public Health Service, Department of Health and Human Services

*Serving as Acting Administrator, Health Resources and Services Administration, since June 29, 1985.

2. January 1981 - September 1982
Acting Administrator
Health Services Administration, Public Health Service, Department of Health and Human Services

3. 1976-1982
Deputy Administrator, Health Services Administration, Public Health Service, Department of Health and Human Services

4. 1973-1976
Director, Office of Regional Operations
Office of the Assistant Secretary for Health
Department of Health, Education and Welfare

5. 1971-1973
Associate Administrator for Management
Health Services and Mental Health Administration, Department of Health, Education and Welfare

6. 1968-1971
Assistant Administrator for Management, Health Services and Mental Health Administration, Department of Health, Education and Welfare

7. 1966-1968
Executive Officer, Public Health Service, Department of Health, Education and Welfare

8. 1962-1966
Assistant Executive Officer
Bureau of State Services/Environmental Health, Public Health Service, Department of Health, Education and Welfare

9. 1960-1962
Chief, Management Advisory Branch, Bureau of State Services/ Environmental Health, Public Health Service, Department of Health, Education and Welfare

10. 1957-1960
Management Analyst, Public Health Service, Department of Health, Education and Welfare

11. 1955-1957
Management Analyst, Department of Agriculture

12. 1951-1955
Occupational Research Analyst, Department of the Navy

AWARDS

DHEW Superior Service Award - 1969
DHEW Distinguished Service Award - 1972
Senior Executive Service Bonus - 1980, 1981
Presidential Rank Award - 1982
Senior Executive Service Bonus - 1983, 1984, 1985

REQUEST FROM PUBLIC HEALTH SERVICE

Senator WEICKER. Mr. Kelso, can you tell me what you, as the Health Resources and Services Administrator, requested of the Public Health Service [PHS] for your 1987 budget?

Mr. KELSO. What HRSA asked the Public Health Service?

Senator WEICKER. Yes.

Mr. KELSO. We asked for a total of $1,563,647,000.

Senator WEICKER. We are at $1.182 billion, and that is the Office of Management and Budget [OMB] figure.

Mr. KELSO. Yes.

Senator WEICKER. Principally, where did OMB and you differ?

Mr. KELSO. Primarily in health professions, and in some other programs, but primarily health professions.

GERIATRIC TRAINING INITIATIVE

Senator WEICKER. Last week, the Director of the National Institute on Aging testified before this subcommittee and reported that the 65-year-old population will double by the year 2020; the 85-year-old population will double by the year 2000. Recognizing that we are not prepared to deal with such a drastic increase in the elderly population, the geriatric training initiative was started for the first time in 1985 with $5 million. You propose to rescind all the money left after the Gramm-Rudman cut for 1986, and you propose not to fund this program at all in 1987.

Would you like to tell me or give me a better idea as to how we prepare for this increase in the aging population?

Mr. KELSO. Mr. Chairman, I think that this is included in the rationale for everything that is being eliminated in health professions. As you know, these programs started in the 1960's and the 1970's, were very

adequately funded, were very effective, and we have gotten to a point where there is at least an adequate number of physicians and other health professionals. We believe that we have built an infrastructure in these programs that will carry them on in the future. Quite frankly, given the competition for Federal dollars, the programs had to be eliminated.

I might say, Mr. Chairman, on the figure that I gave you of what we asked PHS for, the echelons above me were under some restraints and constrictions that I was not under. So that does account for some of that difference.

Senator WEICKER. Let me ask this first question. Are you aware as to, out of 122 medical schools in the country, how many have actual courses in geriatric training?

Mr. KELSO. I will ask Mr. Hatch, if he will, to answer that question.

Mr. HATCH. Mr. Chairman, the number that have programs in geriatric training has been increasing. I will provide you, for the record, information from a review that was done a couple of years ago. I think the medical schools and the other health profession schools are very much concerned and alert to the issues that you have raised in this area, and they have been improving their programs.

Senator WEICKER. I am not saying that there aren't some courses being taught. I think there are about 30 that teach some courses in this area. I think that there are still only two with departments in the medical schools. Some are teaching some courses.

First of all, are any of you disputing the figures that I just gave you?

Mr. KELSO. No, sir; I have no basis to dispute them.

Senator WEICKER. Those are the figures.

I would like to know what programs, what initiatives—you referred to some programs that we started in the 1960's and 1970's. I would like to know what it is that has been done specifically to address this problem.

Mr. KELSO. In this budget?

Senator WEICKER. Yes.

Mr. KELSO. We are not asking for any funds in health professions.

[The information follows:]

GERIATRIC EDUCATION

In 1983 (the most recent survey available), about 90 percent of the 100 responding medical schools (out of 126) indicated some activities in geriatric education. Seventy-two percent of the schools had some required time for geriatric education (for example, a component in the required introduction to medicine course or, in a few instances, a geriatric rotation). Nineteen percent had only elective curriculum and 9 percent had no geriatric curriculum time. (These findings were reported in the Journal of American Geriatric Society, 33:(2), pp. 133–135, 1985.)

Medical schools are organized in a variety of ways to provide geriatric training, from Department level focus to no specific administrative unit. In most medical schools, geriatrics is taught by faculty from major existing departments. The 1985–86 Directory of American Medical Education lists two departments of geriatric medicine and 28 divisions of geriatric medicine or gerontology.

PERSONNEL NEEDED FOR GERIATRIC TRAINING

Senator WEICKER. How long do you think it would take to gear up in terms of personnel to handle these figures here?

Mr. KELSO. I really couldn't tell. Could I submit that for the record. I will really have to think about that. I couldn't say off the top of my head.

[The information follows:]

GERIATRICIANS

In general, the elderly tend to require more medical services than younger adults. There were approximately 165 million visits to physicians made by the elderly during 1980. It is projected that this figure will increase 40 percent by the year 2000. This represents an estimated 230 million visits annually. It is expected that the major portion of the health care services for the elderly in the future will be provided by primary care physicians who are adequately trained in the case of the elderly. Two independent studies have estimated that an additional 7,000 to 10,000 geriatricians would be needed by 1990 for teaching, consultation activities, and a limited amount of primary care (Report to Congress on Education and Training in Geriatrics and Gerontology, 1984).

There are multiple factors impinging on the timeframes that will be required to provide appropriate numbers of practitioners to care for the elderly, for instance, the mix of health providers needed to deliver the services and the method of how these services will be reimbursed. A departmental study (Report to Congress on Education and Training in Geriatrics and Gerontology, 1984) indicates that the minimum target in 1990 for well-prepared geriatric physician faculty in medical schools is 600; in the year 2000, the target is 1,300 physician faculty.

TRAINING TEACHERS IN GERIATRIC MEDICINE

Senator WEICKER. Counsel indicates to me that he has seen figures that we should be training 900 teachers within the next 20 years in geriatric medicine, never mind having the teachers in place after they have learned going ahead to pass on their knowledge to the doctors.

What I am saying is, there couldn't be a more classic demonstration of fiscal irresponsibility. For purposes of these hearings, I will leave my heart at home. You are not going to find me the great bleeding heart liberal. Let's just do it on a sound budgetary basis.

We know that the statistics are doubling in these populations, over 65 and over 85. Two medical schools in the country out of 122 have departments to go ahead and specialize in this particular area. The need is clear, there are close to 1,000 teachers that are required in geriatric medicine, and we know that.

What I am trying to do, and my colleagues in the Senate and the House, was to start on a small basis to focus in this area, this specialized area of medicine in preparation for those numbers. Obviously, the $5 million was to increase, but this was to get things going and get some sort of a learning curve going here before we started to throw a lot of money out there, and so we would have the experience. That is knocked out.

I would like to know from you how you feel that this is going to be handled. You feel that it can be handled through competition? I don't know of any Federal program that is going to be able to handle it. What are we going to do?

Mr. KELSO. The Federal Government is not the only group that is involved in this. There are States, and there are other organizations. It is not just the Federal Government that is involved.

REDIRECTION OF RESOURCES

Senator WEICKER. The problem with competition right now, apparently, for whatever reason, there isn't the impetus economically to go ahead and redirect our resources, our personnel resources toward anticipating this problem and eventually being able to handle it. So what are we going to do, wait until the problem is on top of us?

Mr. KELSO. As I said, there is nothing in this budget, and there are other organizations involved. I am here to explain this budget, and there isn't anything in there.

Senator WEICKER. What would you do?

Mr. KELSO. What would I do?

Senator WEICKER. Without having somebody else tell you what to present in the way of a budget, what do you feel should be done?

Mr. KELSO. Mr. Chairman, I am here to defend this budget, and there is nothing for this in the budget. I just don't think that my personal views are necessarily germane. We can enter something in the record, some statement regarding that, but I wouldn't want to do it off the top of my head.

[The information follows:]

GERIATRIC TRAINING

Competence in health care for the elderly should be fostered in the total health care system. It is believed that market forces, private sector interest, and increasing State/local government interest will result in providers shifting resources to the elderly. This shifting will continue to motivate health professions schools to give appropriate attention to the preparation of physicians and other health professionals to provide necessary services. Increased awareness of demographic changes and the nature of health needs of the elderly are leading institutions of higher education, professional associations, State and local governments, and the private sector to examine the relevance of their current efforts to the increasing demand for services to the elderly. This evidence ranges from regional meetings of medical and other health professions schools, increased use of nursing homes and other settings for teaching, and earmarked State support for geriatric education, to local initiatives to help family and other care givers assist the elderly. National organizations such as the Robert Wood Johnson Foundation and the Beverly Foundation, as well as various local foundations, are also providing support to these endeavors.

BUDGET INITIATIVE

Senator WEICKER. I want the record to show that this budget, and I won't attribute it to Mr. Kelso, but that this budget, at least in terms of the aging population, is a disaster fiscally. The out-year costs of trying to play catch up ball to the training of personnel to handle the increased aging population is going to be just disastrous in terms of the financial implications.

I don't think that there is a person in this room or without that knows that when you see a problem, and the problem is well delineated

without any dispute by anybody, when you see that problem, by far and away the best way to handle it in terms of the quality of delivery of services, and in terms of the finances is to get on it early.

This administration has consistently done nothing in this area. The initiative was put in by the committee and supported by the House. It will be in there again this year. It gives me the opportunity to reemphasize the fact that the administration, in conjunction with those who were supporting Gramm-Rudman, indicated that once they exempted Social Security from Gramm-Rudman, the problems of the elderly were taken care of. Who wants to collect their Social Security check and live if there is no quality of life? That ought to be explained to the elderly, the fact that when they grow old, and there is no roof over their head, it is not the responsibility of this particular subcommittee, nor is there the health care available to them, nor the results of the research and development that would go into an analysis, and hopefully the alleviation of their various ills and afflictions.

Good government anticipates crisis, it does not react to it. That is the essence of what is being done here in the geriatric area.

COMMUNITY HEALTH CENTER BASE GRANTS

You know of the good work being done by community health centers to lower per capita hospital admission rates and to lower Medicaid reimbursements significantly.

For the last several years, we have complained of your consistent refusal to increase the average base grant award of the centers in spite of the fact that the appropriation increased by $17 million from 1984 to 1985, and increased by $18 million from 1985 to 1986.

In fact, I understand you have approved and then refused to fund two computers, one costing $43,000 and the other $28,000, for two centers in Connecticut. While you require the centers to be more cost effective and efficient, you deny them the method by which to accomplish these goals.

How long will it take you to have computers in place in Hartford and Bridgeport?

Mr. KELSO. I am going to have Dr. Martin respond to that.

Senator WEICKER. All right.

Dr. MARTIN. Your first question, the base grant question, has come up in prior years. The actual number of users of community health centers in the State of Connecticut increased by 18 percent. The base grants for community health centers have increased in Federal dollars by 37 percent, and the overall funds by 33 percent.

Both of the computers to which you refer have been approved, and it is simply a question of making the funds available to put in those particular computer systems.

The program and the agency are very supportive of modernizing data systems capabilities in health centers, and we have done a great deal in that area in the last 4 or 5 years.

HEALTH EDUCATION ASSISTANCE LOANS

Senator WEICKER. Last year, we inserted bill language to ensure that the Office of Management and Budget—incidentally, one thing, in the preparation of your budget, Mr. Kelso, I can assure you personally, there will be no block granting of the health centers, not this year.

Last year, we inserted bill language to ensure that the Office of Management and Budget would adhere to the loan guarantee ceiling of $275 million, health education assistance loans. Your proposal for 1987 would reduce the amount of financial assistance available to medical students to $100 million.

Are you complying with the law stated in the continuing resolution with respect to apportionment for the HEAL Program?

Mr. KELSO. Yes, sir; we are. We have a general counsel's opinion. We will not be seeking apportionment, and we hope to have those funds out within the next week or so for fiscal year 1986.

The $100 million ceiling in 1987 is a reflection of a concern on default rate in the future.

DEFAULT RATE

Senator WEICKER. A concern for the default rate in the future. I don't understand that.

Mr. KELSO. We are concerned about the number of defaults. The feeling is that if the ceiling is lowered, we will be better able to monitor the program and be sure that there are fewer defaults in the future.

Senator WEICKER. Do you mean to tell me that you run a program like this on the basis of the default rate, and that is the driving thing?

Mr. KELSO. There is a concern about that, and I think that it is correct.

As far as the apportionment in 1986, there is no problem.

Senator WEICKER. Don't you have the capacity to go ahead and collect on these loans?

Mr. KELSO. Yes; but there are defaults.

Senator WEICKER. I dare say there are. I suppose the ultimate would be to have no loans at all, then you wouldn't have to worry about the default rate or about collecting the loans.

Where is this dividing line? I don't understand this. I have never heard anybody come before this subcommittee and say, we are going to go ahead and, in effect, define the parameters of the program based on the default rate. I don't understand that. Not on the basis of need, as to whether or not these persons need it, or giving an opportunity for those who normally wouldn't have the opportunity, the middle- and lower-income students, to get into a program, but on the basis of the default rate.

Mr. KELSO. We do have the HPSL and NSL Programs still on the books.

DEFENSE OF THE BUDGET

Senator WEICKER. Are you really committed to this job that you have right now? Is it driven by numbers, or is it driven by what needs to be done?

Mr. KELSO. My task today is to defend the President's budget.

Senator WEICKER. Are you a budget officer? We have OMB types around here, we don't have to worry about them. When I have you before me, I look more to the matter of the substance of these programs than the budgetary aspects, that is for OMB.

Mr. KELSO. It is my job to defend this budget.

Senator WEICKER. No; it is OMB's job to defend the budget. It is up to you to explain why these things are being done. You are telling me that, on the HEAL Program, the reason for the cutback is because of your apprehension as to those who might default.

Mr. KELSO. That is one concern, yes.

Senator WEICKER. What are some other concerns?

Mr. KELSO. That is the concern. Quite frankly, we are concerned about defaults and, given the deficit, we want to be sure that we manage the money correctly.

Senator WEICKER. Senator Proxmire.

GERIATRIC ACADEMIC UNITS

Senator PROXMIRE. Thank you, Mr. Chairman.

Mr. Kelso, last year's justifications state that in 1985 the Health Professions Special Education Initiatives Program supported the establishment of 24 geriatric academic administrative units. This year's justifications indicate that you only supported the establishment of 16 units in 1985. Why the discrepancy?

Mr. KELSO. I will have to ask Mr. Hatch to respond to that.

Mr. HATCH. Senator Proxmire, the actual number that we would be able to fund in 1986, based on the amount appropriated in 1986, without reference to the rescission, would be about 20. The reason for the difference between 20 and 16 is that 4 of the centers that we started 3 years ago will be going off of Federal funding this year. We expect to fund about 20 again this year.

Senator PROXMIRE. My problems come from the statements in the 1986 and the 1987 justifications. You say, on page 46, "In 1985, the program supported the establishment of 24 geriatric academic administrative units to provide multidisciplinary clinical instruction and training in geriatrics to health profession students so they will be able to treat the special health problems of geriatric patients."

Then on page 41, this year, you say, "In 1985, the Bureau also supported the establishment of 16 geriatric academic administrative units."

Mr. HATCH. Sixteen new ones last year, Senator.

Senator PROXMIRE. So the 24 was incorrect, is that right?

Mr. HATCH. There were a total of 4 that were continuing from the previous year and 16 new for a total of 20 in 1985. In 1986, we would support about the same number, subject to the rescission.

Senator PROXMIRE. I don't want to belabor that, but it looks like the statement in the 1986 justification was incorrect when you said 24. Is that right?

Mr. HATCH. There would be 16 continuations, and approximately 4 new projects in 1986.

NATIONAL HEALTH SERVICE CORPS FIELD STRENGTH

Senator PROXMIRE. Last year you estimated a total National Health Service Corps [NHSC] field strength of 3,501 in fiscal year 1986. Your current field strength estimate for 1986 is 3,304. What caused the shortfall?

Mr. KELSO. Dr. Martin will respond to that.

Dr. MARTIN. Senator Proxmire, there were basically two factors. Over the last 2 years, we have encouraged a large number of the undertrained physicians to complete their training. In any given year, when we make an estimate for the next year, we have to estimate the number who will continue their training. We were very successful in the last year in getting a large number of individuals who were preparing to serve 1 year of training to go ahead and complete their training.

So I would say that the decrease in the actual field strength is simply moving 150 or so young doctors further down the pipeline, so that when they are ready to serve, they will have fully completed their training.

NHSC SCHOLARSHIP DEFAULT CASES

Senator PROXMIRE. Last year, your predecessor supplied a table for the record indicating the status of National Health Service Corps scholarship default cases referred to the Justice Department. The table indicated that a total of $9.9 million in principal and interest was owed to the Federal Government, but that only $1.5 million of the total had been collected or would be collected under a court judgment.

Has that situation improved? Can you give us a rough idea of the current status of those cases?

Dr. MARTIN. Yes, Senator Proxmire; we can provide for the record a specific update. Judge Murphy, since he has assumed responsibility at Justice for this activity, he has been quite aggressive. I think that we have right now in excess of 120 cases under active litigation, and we can provide the numbers for you. I think that we are going to recover well over $12 million through Justice Department activity. There has been a substantial improvement.

Senator PROXMIRE. Last year, we were told that the names of defaulting NHSC scholarship recipients would be released to education institutions so that they could take part in the debt collection process. Have the names been released?

Dr. MARTIN. Yes, sir.

[The information follows:]

NATIONAL HEALTH SERVICE CORPS SCHOLARSHIP PROGRAM

SUMMARY OF DEPARTMENT OF JUSTICE CASE LOG

Status	Total debtors	Principal	Interest	Judgment amount
No Department of Justice action to date	64	$3,164,034.71	$2,533,530.12	
Complaint will be filed	12	753,339.94	509,083.40	
Complaint filed	58	2,845,990.57	2,078,740.18	
Prejudgment agreement:				
Paying:				
Not compromised	8	187,443.50	106,054.35	
Compromised	5	168,566.00	108,120.26	
Not paying—not compromised	3	46,227.61	13,924.07	
Compromised	1	21,060.00	15,298.99	
Consent judgment:				
Paying—not compromised	14	395,491.61	203,432.52	
Not paying—not compromised	8	211,706.56	74,483.84	$221,173.89
Paying—compromised	2	57,220.00	35,433.09	45,021.00
Not paying—compromised				
Default judgment:				
Paying	3	37,724.20	9,896.62	45,901.43
Not paying	21	585,514.12	356,267.05	918,206.82
Pending service placement	13	605,224.83	491,675.67	
Filed bankruptcy—in litigation	7	218,069.27	121,360.10	
Began service obligation	1	234,231.00	141,932.19	
Active	220	9,531,843.92	6,799,232.45	1,230,303.14
Paid in full:				
Not compromised	15	260,148.60	109,563.03	339,313.33
Compromised	14	265,411.49	116,642.51	158,678.37
Completed service				
Discharged bankruptcy	1	22,126.64	9,319.37	
Death certificate	3	46,537.36	16,664.45	
Settled	33	594,224.09	252,189.36	497,991.70
Total	253	10,126,068.01	7,051,421.81	1,728,294.84

HEALTH MAINTENANCE ORGANIZATIONS

Senator PROXMIRE. In comparing this year's justifications with your 1985 justifications, I note that the number of health maintenance organizations [HMO's] has increased from 360 to 500, an astonishing increase in just 1 year. It is a growth of almost 40 percent in 12 short months. Enrollment jumped from 15 million to 19 million. Can you tell us what caused that remarkable growth?

Mr. KELSO. I think that the HMO concept has come into its own. It is now accepted. I think that you will see increasing utilization of the HMO concept.

Senator PROXMIRE. What resources in dollars and personnel will you devote to HMO activities in 1987 as compared with 1986?

Mr. KELSO. The Federal Government has no resources to put into HMO's. Our role is one of monitoring HMO's, and certification for dual choice, and that kind of thing.

Senator PROXMIRE. I am talking about that. What resources will you be putting into monitoring and certification?

Dr. WHITESIDE. We have about $4.5 million in support of those activities.

Mr. KELSO. We have about 80 people involved in that.

Senator PROXMIRE. How has that changed from 1986 to 1987 in view of the enormous increase?

Mr. KELSO. I don't think that there has been any change, it has been level staffing.

Senator PROXMIRE. Shouldn't that require more, the fact that you have a much bigger operation?

Mr. KELSO. The thing that they are doing, they are certifying HMO's for dual choice and competitive medical plans for certification under the Health Care Financing Administration [HCFA]. That really isn't related to the increase of the HMO movement generally throughout the country.

Senator PROXMIRE. Thank you.

Thank you, Mr. Chairman. I have some questions for the record.

HEAL ALLOCATION

Senator WEICKER. Let's get back to the HEAL loans. I gather you still have not gotten the allocation out.

Mr. KELSO. No; as I indicated, it should go out in the next couple of days.

Senator WEICKER. That is roughly 4 to 5 months overdue; right?

Mr. KELSO. We have the first two quarters out. The next allocation will be for the last two quarters of the fiscal year.

Senator WEICKER. Counsel indicates to me that the bill language indicated that there should be one allocation; is that correct?

Mr. KELSO. There should be no apportionment. We should not have to go to the OMB and ask for it quarterly. We did that on the first two quarters. We will not ask for it that way in the last two quarters. The last two quarters will go out in the next few days.

COMMUNITY HEALTH CENTERS

Senator WEICKER. Senator Proxmire had a question which is identical to the one that I was going to ask. I will use his language, and he said, "I note that this year the number of community health center grantees will drop from 590 to 550, and the population served will fall from 5.2 million to 5.15 million. What impact will this reduction have on the health of low income Americans?"

Dr. MARTIN. Well, Mr. Chairman, a large part of the changes in the number of actual health centers is related to the consortia and combination of centers. The number of actual service areas that will lose services from health centers is kept very, very low, and only those areas where there are alternatives would we not have some type of community health center mechanism. For example, it is possible to have three centers combined into one, or if we defund one, augment two others to cover the population.

I think the impact on underserved communities is best reflected by the success of the program. In fact, a very large number of underserved people continue to be served and are provided a much wider and more comprehensive range of services than in the past, so that the unit cost for each patient, based on those services, continues to increase. Maintaining the level of services to the 5 plus million highest need people, I think, is a success, particularly given the emphasis on increasing the services, having a responsibility for vertical services like admitting your own patients, and the like.

PRIMARY CARE BLOCK GRANT

Senator WEICKER. Why if the program, in your words, is such a success, are you seeking to block grant it?

Dr. MARTIN. Because we feel that the relationship at the local and State level, with the activities that States already carry out, is critical. In fact, they invest a great deal more than we do in that kind of activity. The populations at risk are better served if those resources are brought together at the level where the services are, in fact, provided.

The administration feels very strongly that this type of activity is best carried out, and most appropriately carried out, by States. It has been a firm policy of the administration for 5 years.

NURSE TRAINING

Senator WEICKER. Last summer, the President signed legislation authorizing nurse training programs for 3 years. Now, a few months later, you are requesting that the $63 million appropriated for these programs in 1986, $57.4 million, be rescinded, and that nothing be appropriated for any of these programs in 1987.

How do you explain the 1986 rescission proposal and the 1987 cut?

Mr. KELSO. It goes back to what I said at the beginning, I think, Mr. Chairman. This is primarily a fiscal restraint priority judgment.

Senator WEICKER. In 1984, in the fourth report to the Congress on the status of health personnel, you recommended continued Federal support for nursing education programs to assist in filling the unmet needs for nurses prepared as teachers, administrators, and clinical specialists. Do you go back on that report?

Mr. KELSO. No, sir; I don't go back on the report, but as I said, this is a fiscal constraint priority judgment.

Senator WEICKER. They don't show fiscal restraint over there in the Defense Department.

Mr. KELSO. I am not in the Defense Department.

BUDGET ADVOCACY

Senator WEICKER. No; you are supposed to be advocating your particular Department, and that is exactly the point I am trying to make. Are you advocating your Department's needs, or are you advocating a budget, in effect, which is guaranteed to go ahead and come up with a shortfall in terms of those needs?

Mr. KELSO. I have plenty of opportunity within the Department to advocate my point of view, but I am here to defend the President's decision.

Senator WEICKER. Even in light of the report that you presented to us in 1984.

Mr. KELSO. That is correct.

Senator WEICKER. That is rather strange advocacy, don't you think?

Mr. KELSO. No; I don't think so. I think that it is my job to defend the budget.

Senator WEICKER. Despite the facts.

Mr. KELSO. I think the judgments that have been made, again, reflect relative priorities in a very tight fiscal situation. Decisions had to be made.

Senator WEICKER. I don't see that there is much point in continuing the questioning because I think the next time when your Department comes up here, you might just as well have the OMB sitting in your place. As to the matters of substance, apparently, they receive no consideration. It is just a question of the budget.

Senator Harkin, I apologize, I didn't see you there.

Senator HARKIN. Mr. Chairman, I have no questions.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. There will be other questions presented to you for response to the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

INFANT MORTALITY/COMMUNITY HEALTH CENTERS

Question. It has been called "the Third World phenomenon here in the U.S." That is, babies are dying because of infectious diseases, poor nutrition, and lack of access to basic medical care.

While the infant mortality rate overall fell slightly over last year, each year 40,000 infants still die.

Your proposal to block grant and reduce funding for the community health centers guarantees that at least 50 infants will die from lack of care and that over half a million people (60 percent of whom are women and children), with no health insurance and no access to health services, will not receive basic medical care in 1987.

Have you calculated how much special services will cost for the lifetime of a baby born with a defect which is preventable?

Answer. Before the question can be properly answered it is necessary to take issue with the statistics that were used in the introduction to the question. First, although we are confident in the ability of Community Health Centers to provide high quality primary health care services to underserved populations, we believe that it would be professionally improper for us to go before the Congress and to guarantee to save a specific number of lives per year in a specific segment of the service population. Conversely, we cannot guarantee that by not providing the services a specific number of lives would be lost. Second, despite a reduction in overall Federal support below the 1985 level, and even if the States were not to compensate for that reduction, the half-million figure far exceeds the number of people who might be affected by the reduction. One reason for this is that the block grant approach permits a more efficient and effective use of available resources, Federal, State, local government and private, and would therefore mitigate against any reduction in Federal support.

Like unpreventable defects, preventable defects vary in their severity and in the amounts of money required to correct them or to compensate for them. Some might require only minor surgery and others might require a lifetime of intensive care and therapy which would cost hundreds of thousands to millions of dollars.

Question. What suggestions do you have for these additional half million people who will no longer be able to receive services?

Answer. I do not have any facile suggestions for anyone who has no health insurance and is economically not well off, whether or not he is in an area where a Community Health Center could legally be placed.

GERIATRIC TRAINING INITIATIVE

Question. It is estimated that America's population of 75 and older will increase by over 50 percent by the year 2000 -- just 14

years from now. The population group 65 and older will increase 27 percent, and those 55 and older will increase by 19 percent.

There is a severe shortage of physicians and health professionals who are trained to meet the special needs of our growing elderly population.

We started a Geriatric Training Initiative for the first time in 1985 with $5 million, because, prior to that time, we had 2 -- out of 122 -- medical schools offering courses preparing doctors to deal with the special area of geriatrics. My idea translated into 24 medical schools with programs.

You propose to rescind all the money left after the Gramm-Rudman cut for 1986, and you propose not to fund this program at all in 1987

How are we going to prepare for the health needs of this increased number of older people who will need care?

Answer. Increased awareness of demographic changes and the nature of health needs of the elderly are leading institutions of higher education, professional associations, State and local government, and the private sector to examine the relevance of their current efforts to the increasing demand for services to the elderly. This evidence ranges from use of nursing homes and other settings for teaching, and earmarked State support for geriatric education to local initiatives to help family and other care givers assist the elderly. National organizations such as the Robert Wood Johnson and the Beverly Foundation, as well as various local foundations, are providing support to these endeavors.

Question. How do you see the elimination of this $5 million investment as saving money in the long run?

Answer. It is necessary that broad reductions be made in many program areas to achieve the progress needed in reducing deficits.

PRIMARY CARE TRAINING

Question. Last year we provided $124.4 million for 12 small programs designed to help train students for low-paying public health positions; to become family practitioners, physicians assistants and rehabilitative medicine specialists. Included here is $25.5 million for the principal federal program designed to increase the numbers of underrepresented minorities and other disadvantaged individuals interested in pursuing a health career.

These programs are described by you as a key part of the national goal of adequate health care for all Americans -- from getting minorities into the health professions to getting doctors to locate in rural areas and the inner city. Mr. Kelso, I think even you will admit that in certain disciplines and specialties there is still a shortage. Yet, every one of these programs is proposed for zero funding.

Are we going back to the good old days when only the rich could go to medical school?

Answer. As I previously mentioned, we do have some shortages in certain specialities and in some geographic areas. We continue to provide student support through the Health Education Assistance Loan (HEAL) program. Needy students will continue to have access to the Health Professions Student Loan and Nursing Student Loan programs. Also, States, schools and foundations have sources of financial aid for needy students.

Question. Are we giving up on trying to get doctors for rural areas or inner cities which have none?

Answer. We are continuing efforts to get doctors for rural areas and inner cities. In fact, the number of primary care health manpower shortage areas has shown a steady decrease during the last few years, i.e. a 12 percent decrease from 2,150 HMSAs in June 1983 to 1,897 HMSAs in December 1985. Currently National Health Service Corps personnel and health personnel sponsored by State and local governments are being assigned to practice in these areas. Much of the noted decrease in HMSAs is attributed to these personnel remaining in the HMSAs after completing their assignments. We are encouraged by this. Realistically, we believe we will never be able to entirely eliminate all pockets of need for physicians and other health personnel. There are just some geographical areas that we cannot provide for and support the facilities for maintaining a physician's practice and thus, do not attract health care providers.

NURSE TRAINING PROGRAMS

Question. Just last summer the President signed legislation authorizing nurse training programs for three years. Now, a few months later, you are requesting that, of the $63.0 million appropriated for these programs in 1986, $57.4 million be rescinded -- and that nothing be appropriated for any of these programs in 1987.

How do you explain the 1986 rescission proposal and the 1987 cut?

Answer. The rescission is necessary as a part of the President's overall reform plan to curtail Federal government spending. At the time the authorization legislation for nurse training programs was signed into law, the Congress had not as yet mandated States deficit reductions. We are, in light of this subsequent legislation, asking Congress to re-assess spending in the nurse training area.

Question. If you reject these nurse training programs, what alternatives do you propose to resolve the distribution problem?

Answer. In addition to using the resources gained by the past Federal support to nursing education institutions; it should now be the responsibility of States and the private sector to maintain the necessary level of support to continue these functions.

Question. Have you reversed the position which you took in 1987 in the Fourth Report to the Congress on the Status of Health Personnel in which you recommended continued federal support for nursing education programs "to assist in filling the unmet needs for

nurses prepared as teachers, administrators, or clinical specialists?"

Answer. In its reevaluation of competing priorities, the administration was mindful that the past twenty years of Federal support had built and stabilized resources for support of nursing education in educational institutions including programs preparing teachers, administrators and clinical specialists.

Question. How do you propose to increase the number of nurse midwives if all funding for nurse training programs is eliminated?

Answer. Increasing the number of nurse midwives depends less on continued Federal support than on resolution of the very critical malpractice insurance issue and third party reimbursement policies.

HEALTH EDUCATION ASSISTANCE LOAN (HEAL) PROGRAM

Question. Last year, we inserted bill language to ensure that the Office of Management and Budget would adhere to the loan guarantee ceiling of $275 million for Health Education Assistance Loans (HEAL). Your proposal for 1987 would reduce the amount of financial assistance available to medical students to $100 million.

How would this reduction affect the ability of middle and lower income students to finance a medical education?

Answer. The Department has recently completed a Notice of Proposed Rulemaking for the HEAL program which we plan to implement in final regulations as soon as possible. This new regulation will give schools the authority to limit excess borrowing by tying the approved HEAL amounts to unmet need after consideration of other resources available to the student. The implementation of this regulation will assure that limited HEAL funds are appropriately used. In addition, students with financial need will be able to secure loans from the $49 million Health Professions Student Loan revolving fund as well as the Guaranteed Student Loan and other Department of Education loan programs. Students may also qualify for State, private and institutional loan and scholarship programs.

Question. Are you complying with the law as stated in the Continuing Resolution with respect to apportionment for the HEAL program?

Answer. The Department is complying with the law concerning the apportionment of HEAL funds. The FY 1986 loan guaranty insurance authority plus the carryover authority from FY 1985 will be allocated to HEAL lenders shortly.

NURSING RESEARCH

Question. The average cost of neonatal intensive care is estimated to exceed $13,000, and almost seven percent of newborns in the U.S. are at risk because of low birthweight. Nursing research on the care of premature infants resulted in treatment that reduced their length of hospital stay by an average of four days. This is just one example of how federal support for nursing research has been shown to save taxpayers' dollars in the long run.

Why is this program of proven effectiveness proposed for elimination in 1987?

Answer. Elimination of a line item for support of nursing should be viewed as an assessment by the Department that studies supported previously were ineffective. Studies like the ones you mentioned should continue to compete successfully for research support from NIH, ADAMHA and NCHSR.

Question. What alternatives do you propose to research programs which help make nursing care more cost effective and technologically advanced?

Answer. We would expect that these initiatives would compete favorably for Federal research support from the NIH, ADAMHA, NCHSR or NSF.

DISADVANTAGED ASSISTANCE

Question. For Fiscal Year 1985 you recommended a $6 million increase for the Disadvantaged Assistance program. You emphasized at that time that these additional funds were needed in order "to maximize the opportunities for minorities and the economically disadvantaged to enter health professions careers." We agreed with you and provided the additional funds. The appropriation now stands at $25.5 million. This year again you request no funding for this program.

What alternative to this program do you have in mind for getting minorities and the disadvantaged to enter health professions careers?

Answer. The alternative to replacing Federal support for the Disadvantaged Assistance program is State-based support and creative private initiatives coupled with continued federal student assistance programs.

NATIONAL HEALTH SERVICE CORPS

Question. This Committee has supported the placement of National Health Service Corps assignees in Community and Migrant Health Centers. This policy makes sense from the perspectives of need and management.

While you have admitted that experience during recent years has demonstrated considerable difficulty in predicting the exact field strength of the Corps, you nevertheless propose a reduction of $11.5 million for 1987 from $58.5 million, the 1986 appropriated level. You state that a reason for this is the overall reduction in health manpower shortage areas. However, the authorizing committees projected a need for some $70 million for this program.

As you are trying to reduce this program, what alternatives do you have in mind for staffing community health centers and for getting health care personnel to locate in rural and inner city areas?

Answer. Emphasis continues to be placed on the assignment of obligors in settings that do not require direct Federal support, via the Private Practice Option (PPO) and the Private Placement Assignment (PPA) employment opportunities. As the number of Health Manpower Shortage Areas (HMSA) designations continue to decrease, the use of the HMSA Placement Opportunity Listing (HPOL) will play an even greater role in making the most effective use of scarce resources available to the NHSC.

Developed in cooperation with a variety of State and local planning and health resource agencies, professional societies and associations, the HPOL insures not only that placement areas are HMSAs, but that NHSC providers will be placed at, working in and be part of an organized system of care to the population at risk which will provide a more viable organization to retain NHSC providers after their scholarship obligation is completed.

Another important step toward the improved management of health services delivery to rural and inner-city areas is the development of an overall strategic plan for the use of limited financial resources. The development of these strategies will require the participation of Federal program officials, representatives of State health departments, and local officials representing health center associations within the State. Plans will focus on coordinated use of BHCDA, State, city and other local public and private resources. Objectives include a review of continuation funding priorities and all decisions regarding new program development including expansions/consortia, and new starts as well as strategic planning and other program activities.

The result of these strategic plans will be to develop and implement courses of action composed of the following four elements: determination of the mission, development of an organizational profile, assessment of the external environment, and matching the organization profiles with an external management. The strategic planning approach would allow for increased staffing, capital investments, improved integration of services, expanded services, and improved access for unserved and underserved high risk populations. The emphasis of the strategy is to maximize resources to increase access and service penetration for these high risk populations in rural and urban areas.

Meeting the future staffing needs of Community and Migrant Health Centers will require a variety of efforts. These will include the continued use of obligated NHSC scholars as well as the recruitment and retention of non-obligated physicians. In addition, Federal collaboration with State health agencies through the cooperative agreement program will provide for State-based manpower clearinghouse functions intended to identify pools of potential physicians wishing to practice in respective States.

PUBLIC HEALTH AND HEALTH ADMINISTRATION

Question. Students who take positions in the field of public health are historically among the lowest paid of the health professions. In order to encourage students, particularly the disadvantaged, to enter the public health field, about $10 million is spent each year for federal support to schools of public health.

The Administration proposes to end funding for these public health and health administration programs in 1987.

What alternatives do you propose in order to attract students, particularly minorities and the disadvantaged, to the public health field?

Answer. With the growing institutionalization of previously Federally supported public health and health administration programs by training institutions plus the increased participation of State and local governments and the private sector in programs which foster minority support in the health professions, we feel that it is time to shift the focus of responsibility to these entities.

Question. How will the loss of these program funds affect the schools of public health now receiving these grants?

Answer. We do not anticipate a serious adverse impact. We believe these programs to be institutionalized into the public health educational system.

HEALTH PROFESSIONS FINANCIAL DISTRESS

Question. Meharry Medical and Dental, Tuskegee and Xavier have received Advanced Financial Distress program funding for the past several years. These health professions schools receive grants to meet costs of operation to the extent necessary to remove them from serious and long-standing financial instability. These four schools are responsible for educating a significant portion of the black health professionals in this country. $4.1 million was appropriated in 1986. You propose elimination of this funding in 1987.

How will the loss of these funds affect these four schools?

Answer. Longstanding Federal financial support, over a period of some 15 years, was provided so that the four schools would remain open and have sufficient time to become educationally and financially stable. They have made progress toward attaining the goals specified in their financial plans by increasing tuition, expanding private fund raising, attracting new senior staff and implementing financial planning systems. We do not anticipate that elimination of the $3 million in FY 1987 for the final year of support will have a serious impact on their ability to continue operations.

Question. How would the termination of this program affect the future supply of black health professionals?

Answer. We do not anticipate a serious adverse impact.

HARTFORD ACTION PLAN ON INFANT HEALTH

Question. In certain sections of Hartford, the rate of infant mortality is 29.5 compared to about 11 percent for the entire state.

Last year, an initiative was launched in Hartford to reduce infant mortality and increase infant birthweights. This project is a blending of the city government and 11 Hartford corporations. These folds have begun an outreach program to bring pregnant women and teenagers into care, a community mobilization directed at teen pregnancy issues involving church and civic groups and a health provider package -- linking all public and private, nonprofit health providers. Maternal and Child Health Block Grant funds are being used as the catalyst in this program.

Forty thousand infants nationwide still die each year.

Has your agency taken a look at this program to see how it might be duplicated, or what efforts is the agency making to find innovative ways to attach the infant mortality/low birthweight problem?

Answer. We have not reviewed the Hartford action plan you refer to. However, we are reviewing and seeking to replicate on a national basis those approaches to improving services for high risk mothers and infants which have proven successful in reducing infant mortality and the incidence of low birthweight infants. We will initiate contact with the Hartford city government regarding the action plan. As I'm sure you can appreciate, there are many innovative programs underway at many levels throughout the country and the task which confronts us in the Department and Public Health Service is one which requires a major program of review, implementation and information dissemination. Our major focus for these activities is in the Public Health Service where we have given the issues of infant mortality and low birthweight the highest priority in terms of use of discretionary funding and availability of consultative and technical assistance to States and localities concerned with improving services for the high risk mother infant. Additionally, we are utilizing the service of non-Federal experts as members of Infant Mortality Review Teams which are available to provide on-site review of programs and provide recommendations for the improvement of services. In summary, we have mobilized the resources available to us to address the problems of infant mortality and low birthweight.

Question Submitted by Senator Arlen Specter

HEALTH PROFESSIONS PROGRAMS

Question. I am deeply concerned that the proposal to discontinue the health professions education subsidies in FY 1987 will adversely affect women, minorities, and economically disadvantaged individuals who wish to enter the health professions. I am also concerned that although in general, we may have an adequate supply of nurses and physicians, we may still have serious shortages in specialties and subspecialties. Can you provide assurance that the lack of financial support for the health professions will not deny access of the disadvantaged to an education, or that lack of this support will not increase current shortages in certain specialties and subspecialties?

Answer. Federal efforts in support of health professions programs have provided a considerable investment during the last two

decades in increasing the supply of health professionals. While we cannot provide assurances, we believe that many health professions programs, including the Disadvantaged Assistance program, will be institutionalized by schools and that during times of Federal fiscal constraints non-educational institutions now conducting programs, with support from the States and the private sector, will continue these programs into the future. In addition, financial student assistance will continue to remain available to minority and disadvantaged individuals who wish to pursue a health career. Approximately $67 million in FY 1986 and in FY 1987 will be available from the health professions and nursing student loan revolving accounts maintained in participating institutions to assist an estimated 37,600 economically needy students each year. Other sources of financial assistance will be available in the Health Education Assistance Loan program and loan programs maintained by the Department of Education. We look to these programs and non-Federal sources as the means to address these important objectives.

Question Submitted by Senator William Proxmire

MIGRANT HEALTH CENTERS

Question. Last year your justifications indicated that a total of 500,000 migrants will be served in 142 centers by the end of 1985, an increase of services to 40,000 migrants in 20 new centers.

This year's justifications talk of 500,000 migrants being served by 125 migrant health grantees.

Has the number of centers serving migrants fallen over the past few months and, if so, what has been the effect on the quality of services provided?

Answer. The number of migrant health centers fluctuate from year to year, but the actual delivery points for health services has not. Mergers and consortia activities account for this.

Enhancement of existing migrant health centers through augmentation of health providers, expansion of health services, development of satellites and integration/coordination of health centers with existing delivery systems has increased the number of migrant farmworkers being served and provided a wider range of health care.

Questions Submitted by Senator Quentin N. Burdick

NATIONAL HEALTH SERVICE CORPS (NHSC)

Question. I am deeply concerned that the budget proposal for FY 87 will further erode the pipeline of Corps physicians. Last year, Dr. Robert Graham testified before this subcommittee that the current glut of health professionals negated the need for a federal commitment to subsidizing the diffusion of health professionals through programs such as the NHSC.

Some of us have a hard time with that idea, and we noted then that while the numbers of professionals may be high, there is insufficient distribution. Rural areas are especially short-staffed.

This situation hasn't changed since last year. In fact, it has worsened. In rural America today, millions of Americans must travel long distances to receive primary care. The Corps and free-standing Corps sites are critical elements of health care delivery to rural areas.

What steps do you propose to take to provide for health care delivery to rural families, given that the Administration is trying to reduce funding and staffing of the NHSC?

Answer. The NHSC program continues to place emphasis on the assignment of obligors in settings that do not require direct Federal support, via the Private Practice Option (PPO) and the Private Placement Assignment (PPA) employment opportunities. As the number of Health Manpower Shortages Areas (HMSA) designations continue to decrease, the use of the HMSA Placement Opportunity Listing (HPOL) will play an even greater role in making the most effective use of scarce resources available to the NHSC.

However, there are many rural areas that, due to social and economic factors, will not be able to obtain needed health manpower from the private sector. These are generally located in the southern and midwest states. To the extent that a sufficient economic base does not exist to support the private practice of health care in these isolated rural areas, where Federal and State payment mechanisms do not sufficiently compensate medical services, these "hard-to-fill" areas will go unserved or underserved. To alleviate the provider shortages in these areas, the HPOL will continue to be used in identifying the rural areas of greatest need.

Developed in cooperation with a variety of State and local planning and health resource agencies, professional societies and association, the HPOL insures not only that placement areas are HMSAs, but that NHSC providers will be placed at, working in and be part of an organized system of care to the population at risk which will provide a more viable organization to retain NHSC providers after their scholarship obligation is completed.

Another important step toward the improved management of health services delivery to rural areas is the development of overall strategic plans for the use of limited financial resources. The development of these strategies will require the participation of Federal program officials, representatives of State health departments, and local officials representing health center associations within the State. Plans will focus on coordinated use of BHCDA, State, city and other local public and private resources. Objectives include a review of continuation funding priorities and all decisions regarding new program development, including expansions/consortia, and new starts as well as strategic planning, and other program activities.

The result of these strategic plans will be to develop and implement courses of action composed of the following four elements: determination of the mission, development of an organizational

profile, assessment of the external environment, and matching the organizational profile with the external management. The strategic planning approach would allow for increased staffing, capital investments, improved integration of services, expanded services, and improved access for unserved and underserved high risk populations. The emphasis of the strategy is to maximize resources to increase access and service penetration for these high risk populations in rural and urban areas.

Meeting the future staffing needs of Community and Migrant Health Centers in rural settings will require a variety of efforts. These will include the continued use of obligated NHSC scholars as well as the recruitment and retention of non-obligated physicians. In addition, Federal collaboration with State health agencies through the cooperative agreement program will provide for State-based manpower clearinghouse functions intended to identify pools of potential physicians wishing to practice in respective States.

Question. If it becomes more difficult for rural Americans to receive primary care, we will see a corresponding increase in the need for acute care. This will naturally result in increased costs to Medicaid and Medicare. Has your department done any studies projecting the increased costs to Medicaid and Medicare that will no doubt result from the decreased availability of NHSC services?

Answer. Presently, there are no studies concerning the possibility of increased Medicaid and Medicare costs for primary care services in rural areas as a result of possible reductions in NHSC services.

Questions Submitted by Senator Daniel K. Inouye

NURSING RESEARCH

Question. What efforts have been made by HRSA to facilitate the transfer of the nursing research activities from the Division of Nursing to the NIH?

Answer. Senior HRSA staff have been actively meeting with NIH regarding the transfer of nursing research activities. An implementation plan for relocation of these functions has been received in the Department and negotiations are underway between HRSA and NIH regarding transfer of staff, extramural funds and direct operating funds.

Question. When do you expect the transfer to take place?

Answer. A specific date for the transfer to take place has not been set. We have recently learned that space has been found at NIH to house the Center.

Question. Has any of the $5 million appropriated by Congress in P.L. 99-88 become available for use by HRSA?

Answer. No, it has not. These funds are currently proposed for rescission.

Question. In light of several reports showing the need for an increased supply of nurses with graduate preparation to serve as researchers and specialists in underserved and underprivileged populations, what is the Administration's rationale for asking for severe rescissions from the FY 1986 appropriation and elimination of the nursing research and education programs for FY 1987?

Answer. Federal support over the past twenty years has substantially increased the capability of schools of nursing to add to the nurse supply. Baccalaureate programs are now firmly established in academic settings and have available to them the same resources as are used for other health disciplines.

Question. What is the Administration's rationale for continually applying the oversupply argument that is correctly used in describing the physician supply/demand ratio to the nursing profession where the argument is incorrect?

Answer. Evidence presented in the Fifth Report to the President and Congress on the Status of Health Personnel in the U.S. found no aggregate imbalance between the nurse supply and requirements in the foreseeable future. The past twenty years of federal support has substantially increased the capability of schools of nursing to add to the nurse supply. Profound changes in the health care delivery system could alter the supply-demand equation, but there is no quantifiable evidence to date to document the impact of such changes.

OFFICE OF ASSISTANT SECRETARY FOR HEALTH

STATEMENT OF DR. DONALD IAN MACDONALD, ACTING ASSISTANT SECRETARY FOR HEALTH

ACCOMPANIED BY:

WILFORD J. FORBUSH, DEPUTY ASSISTANT SECRETARY FOR HEALTH OPERATIONS AND DIRECTOR, OFFICE OF MANAGEMENT

W. HARELL LITTLE, CHIEF, BUDGET BRANCH, PUBLIC HEALTH SERVICE

PREPARED STATEMENT

Senator WEICKER. We will now hear from Dr. Donald Macdonald, Acting Assistant Secretary for Health.

Welcome Dr. Macdonald. Your statement in its entirety will be placed in the record.

[The statement follows:]

STATEMENT OF DR. DONALD IAN MACDONALD

I appreciate the opportunity to appear here today to discuss the 1987 budget request for the appropriations in the Office of the Assistant Secretary for Health (OASH)--the Public Health Service (PHS) Management appropriation request of $110.1 million, the Retirement Pay and Medical Benefits for Commissioned Officers appropriation request of $91.3 million, and the Priority Disease Control and Research appropriation request of $203.5 million. The request to consolidate funding for research and the control of Acquired Immune Deficiency Syndrome is a new proposal in 1987. Previously these funds have been requested by the PHS agencies.

PUBLIC HEALTH SERVICE MANAGEMENT

The budget request of $110.1 million for the PHS Management appropriation includes funding for a number of high priority programs which operate under the direct supervision of the Assistant Secretary for Health. These programs account for $91.3 million or 83 percent of the funding requested in this account. The remaining funds support the overall management and direction activities for PHS. The Fiscal Year 1987 appropriation represents a $10.3M increase over the post-sequester 1986 level. This increase includes net program increases totalling $5.8 million and $4.5 million for restoration of amounts sequestered in 1986.

The request includes $18.8 million of budget authority for the National Center for Health Services Research and Health Care Technology Assessment (NCHSR). This is a $3.3 million or 19 percent increase over the post-sequester level. NCHSR supports an extramural research program of investigator-initiated proposals which undergo peer review. These studies make a significant contribution to the expansion of the knowledge base for health policy analysis. Projects focus on the development of methodologies required for future evaluation of alternate mechanisms for organizing, financing and delivering health care, including the creation and validation of methods for determining cost benefit and cost effectiveness. For example, research supported by the Center has documented the extent to which life style changes reduce heart disease deaths. Another project has developed a computer based patient-specific drug therapy monitoring process which improves the quality of care by helping to define more precisely the medication needs of hospitalized patients and which alerts the prescribing physician to possible adverse interactions with other medications which the patient may be receiving. Another NCHSR funded analysis showed that high cost hospital episodes, defined as costing $7,500 or more for inpatient charges, make up only 5 percent of hospital cases but account for 30 percent of all hospital charges.

This budget request includes an increase of $3 million to support the field work for the 1987 National Medical Expenditure Survey (NMES). Even though the last similar household survey was conducted seven years ago, it remains the best available source of information for questions that are being asked by OMB, CBO, HCFA, the Department and congressional committees regarding health insurance coverage and the use of and expenditures for health care services. The data collected by this new survey will be even more useful as a data base for addressing the health care and health

insurance policy issues of the 1990s. The NMES scope has been broadened to include institutionalized persons and the expenditures associated with them. In this way we will be better able to address the issues raised by the increasing proportion of elderly Americans, the rapid growth of Medicaid expenditures for care provided for nursing homes and facilities for mentally retarded, as well as for public and private burdens of long term care. The survey will provide an opportunity to update HCFA's Medicare capitation rates for HMOs for the first time since the current Medicare Survey was discontinued in the 1970s. It will also collect data for the Indian Health Service on the health, utilization, and expenditures of American Indians and Alaskan natives in a form that will be comparable to the data for the remainder of the population. This medical expenditure survey is a joint venture between NCHSR and HCFA with important participation by NIMH, the Indian Health Service, and elements of NIH.

The User Liaison Program will be continued as an inhouse effort to broker information between State and local officials and health services research centers in the States.

Another important program included in the request is the National Center for Health Statistics. NCHS is the source of much of the information used to monitor the health of the Nation, follow changes in the use of health services, evaluate relationships between risk factors and health outcomes, and generate hypotheses for biomedical research. Among the most readily recognized and utilized data from NCHS are such key indicators as the infant mortality rate, life expectancy, and causes of death. A wealth of other data provided by NCHS is less well known to the general public, but is heavily relied upon by each of the PHS agencies and by researchers and policymakers elsewhere in the Federal government, the Congress, and the research community.

The budget request of $50 million represents a 12 percent increase over the post-sequester level and includes an increase of $3.4 million for the National Health and Nutrition Examination Survey as it approaches the beginning of its changes in the use of health services, evaluate relationships between risk factors and health outcomes, and generate hypotheses for biomedical research. Among the most readily recognized and utilized data from NCHS are such key indicators as the infant mortality rate, life expectancy, and causes of death. A wealth of other data provided by NCHS is less well known to the general public, but is heavily relied upon by each of the PHS agencies and by researchers and policymakers elsewhere in the Federal government, the Congress, and the research community.

The budget request of $50 million represents a 12 percent increase over the post-sequester level and includes an increase of $3.4 million for the National Health and Nutrition Examination Survey as it approaches the beginning of its data collection cycle in 1988. This survey is a unique source of nutritional, physiological, and diagnostic data, collected through specially designed standardized health examinations. These direct physical examinations, including clinical tests and measurements, are the only source of diagnostic data regarding unrecognized and untreated diseases, and are the best source for standardized clinical, physical, and physiological data on the U.S. population. The last cycle of this survey was

completed in 1980, and planning for the 1988 survey is being made in close collaboration with other PHS agencies, the Department of Agriculture and the medical research community. The request for NCHS also provides for the continuation of those data systems that are conducted on an annual basis which include: the National Vital Statistics System, the National Hospital Discharge Survey, and the National Health Interview Survey. As in the past, the level of funding required to support the base program of NCHS fluctuates from year to year depending on the number, and cost, of those periodic surveys that will be conducted in a given year.

Another high-priority program funded in this appropriation is the Adolescent Family Life program. The FY 1987 request of $14.7 million will provide continuation support for the development of innovative, family centered approaches to postpone the onset of teen sexual activity, reduce adolescent pregnancy, develop effective approaches for delivering comprehensive services to the already pregnant adolescent and adolescent parents, and present adoption as a positive alternative to early parenting. Data available on the problem of adolescent pregnancy indicates several disturbing trends: teen sexual activity rates have been rising for most of the past 15 years; sexually active teens are generally not effective or consistent users of contraceptives; and while the teenage birth rate has been declining, there has been an overall increase in the pregnancy rate and a continuing high abortion rate among teenagers. The AFL program is the Department's major focal point for studying the causes and appropriate responses to adolescent sexual behavior, adolescent pregnancy and adolescent parenthood.

The 1987 budget request also includes a total of $7.8 million to continue support for three special-focus activities: health promotion and disease prevention; smoking and health; and physical fitness and sports. These activities are responsible for providing Federal leadership for the prevention of disease and enhancement of health that can be brought about through changes in individual lifestyles and reduction of behavioral and environmental risks. To achieve this mission, the programs foster the development of cooperative relationships with public and private groups and disseminate information via the media, workshops and conferences. In 1987, the Office of Disease Prevention and Health Promotion will focus attention on those 1990 Health Objectives for the Nation where further progress is needed.

In coordination with PHS agencies, the Office of Disease Prevention and Health Promotion will develop and implement a process for establishing health objectives for the year 2000; disseminate recommendations for preventive services in clinical settings; and disseminate the first Surgeon General's Report on Nutrition and Health.

In 1987, the Office on Smoking and Health will undertake a critical evaluation of all the available literature on the health benefits of quitting smoking. This evaluation will serve as the basis for the 1987 Surgeon General's Report on the Health Consequences of Smoking. This report will include an indepth review of the immediate and long term benefits and the clinical effects of quitting smoking. In addition, a significant portion of the report

will review the behavioral aspects of quitting by age, race, sex and the role nicotine plays in this process.

In addition to the above prevention initiatives, the Physical Fitness and Sports activity will continue its highly successful program of encouraging physical fitness for all Americans with program emphasis on youth fitness as a follow-up to the National Youth Fitness Survey. Other areas of particular emphasis are fitness for working women, older adults and special populations. Our budget request for these three programs will provide levels of support approximately equal to those in FY 1986.

We are requesting $18.7 million for the management and direction of the Public Health Service, which restores the $1 million amount sequestered in this activity in 1986.

RETIREMENT PAY AND MEDICAL BENEFITS FOR COMMISSIONED OFFICERS

The Retirement Pay and Medical Benefits for Commissioned Officers appropriation funds retirement payments to Public Health Service Commissioned Officers, payments to survivors of officers who elected to receive a reduced annuity, and the costs of medical care of active duty and retired officers, their dependents and survivors.

The Fiscal year 1987 request of $91.3 million includes a cost-of-living- adjustment of 4 percent scheduled for January 1987. However, a legislative proposal was developed and will be sent to Congress in the near future to postpone the 1987 COLA for a savings of $2.2 million. This is in accordance with a government-wide effort to contain cost-of-living adjustments for Federal retirement plans.

The Administration is also proposing to change this account from an indefinite to a definite appropriation. As a result, the amount requested in 1987 includes a $5.0 million reserve fund which will be available only to the extent necessary to pay costs and benefits not anticipated in the budget estimate.

PRIORITY DISEASE CONTROL AND RESEARCH

I am pleased to present, our FY 1987 budget request for Acquired Immune Deficiency Syndrome (AIDS). AIDS is the name given to a complex of health problems first reported in the U.S. in June 1981. AIDS is caused by a virus that is bloodborne and sexually transmitted. Persons afflicted with AIDS suffer a severe loss of natural immunity against disease, leaving them vulnerable to diseases that are not otherwise a threat to most people. These diseases are often referred to as "opportunistic".

Before getting into our request, I would like to share some statistics with you. By February 24, 1986, CDC had received reports of 17,741 AIDS cases (17,489 adults and 252 children) in the U.S. Of these patients, 9,294 (52% of the adults and 60% of the children) are reported to have died, including 71% of patients whose illness was diagnosed before July 1984. AIDS cases have been reported in all 50 States, District of Columbia and 3 U.S. territories. Ninety percent of the cases reported have been among two groups: homosexual and bisexual men, 73%; and persons who

inject illicit drugs, 17%. In addition, an estimated 500,000 to 1,000,000 Americans have been infected by the HTLV-III virus. From these statistics one can easily conclude that AIDS has become a disease of epidemic proportion and a public health problem unlike any other in recent history. In combating this problem, we have instituted programs for screening all donated blood in this country; we have required that manufacturers modify their procedures for producing clotting factor for hemophiliacs, rendering this life-giving product free of infectious virus; we have implemented major education/information programs to inform the general public and encourage behavior changes by those at greatest risk of AIDS; and finally, we have established an unprecedented program of epidemiological, clinical, and laboratory research in an effort to further understand the disease and develop effective treatment (drugs) and prevention (vaccines).

Drug Development

One of our highest goals is to speed the discovery, development and testing of drugs against AIDS--and to enable the extramural scientific and medical community and a growing number of AIDS patients to participate in these efforts. This effort is most critical to assist those who now have AIDS, others who may later develop AIDS-related symptoms and still more who are already infected by HTLV-III and may become ill in the future. These efforts will be led by the NIH, particularly NCI and NIAID:

- In a joint project undertaken by the Cancer and Allergy Institutes of the National Institutes of Health, drugs are being screened for their antiviral properties. So far, some 200 drugs have been screened, and several are now in early clinical testing at the National Institutes of Health and elsewhere. Several more antivirals have shown promise in preclinical testing and are being readied for clinical trials.

- To multiply treatment studies around the country, the Cancer and Allergy Institutes in December issued a request for applications for funding of National Cooperative Drug Discovery Groups. The awards that will be made in the next few months will support laboratory testing and animal studies to discover new agents that inhibit HTLV-III and that restore or maintain immune function.

- The Allergy Institute has also issued a solicitation for establishment of AIDS Treatment Evaluation Units around the country. We expect to establish ten of these units. At these units, antiviral drugs, immune modulators, and antibiotics will be tested in patients with AIDS and AIDS-related complex. We hope within a year to have up to 2,000 patients in treatment. The best minds--both inside and outside the government--are also being brought together to establish criteria for deciding when a drug has shown enough promise in early tests to warrant compassionate release on a broader basis, even though the ultimate value of the drug still must be established by further testing.

Vaccine Development

A second major goal of the PHS is to develop a vaccine. The production of an HTLV-III vaccine presents numerous challenges. Unlike other virus vaccines, neither an attenuated nor a killed

whole HTLV-III vaccine would be acceptable because of the undesirable presence of genetic material. However, specific virus proteins have been purified, antibody responses have demonstrated, and these antibodies neutralize HTLV-III in the test tube. The vaccine preparations are now being tested in rhesus monkeys. The next step will be to test the safety and efficacy of these preparations in the chimpanzee, followed by challenge with live virus. These activities will be expanded in 1987.

Prevention Activities - Surveillance, Health Education/Risk Reduction and Public Information

Through the CDC, we will continue national surveillance of AIDS, national and international epidemiological studies to identify new risk factors and further define modes of transmission and the development of prevention strategies to control the spread of AIDS. The goal of PHS's control strategy is to reduce HTLV-III transmission by influencing the behavior of people in three specific population groups. The groups include: (1) those persons infected to prevent further transmission; (2) those high risk groups currently not infected; and (3) the general public. The implementation of this control strategy will be carried out principally through: (1) CDC cooperative agreements with State and local health departments to help intensify surveillance and control activities in high morbidity areas and to develop community health education/risk reducation programs in other areas of the nation. (2) CDC hotline activities aimed toward providing up-to-date information on AIDS to the general but concerned public; and (3) significant expansion of the PHS/OASH comprehensive plan to inform the American public about AIDS in order to create a general awareness and understanding of the syndrome, the ways it is transmitted, and the relative threat it poses to various population groups and to the public health.

FY 1987 Budget Request

The 1987 budget requests that a new appropriation be established within the Office of the Assistant Secretary for Health to consolidate the funding requests for AIDS-related PHS activities, except for the Food and Drug Administration (FDA). The FDA budget is reviewed by the Agriculture, Rural Development and Related Agencies Subcommittee. In the past, funds for AIDS have been requested separately by the Centers for Disease Control, the National Institutes of Health, and the Alcohol, Drug Abuse, and Mental Health Administration. This year we are requesting the single appropriation to assist us in coordinating the total AIDS effort. Approval of this request would enable us to respond more quickly to new scientific breakthroughs and related research and control opportunities. This request also includes $350,000 and 5 FTEs for the AIDS coordinator and staff. AIDS coordinator will be responsible for reviewing and monitoring the AIDS activities being conducted throughout the PHS.

Mr. Chairman, for 1987 we are requesting $203.5 million for AIDS, an a increase of $20.3 million over 1986. This request builds on our accomplishments and primarily expands current NIH research activities, including the development of effective vaccines and drugs.

I will be pleased to answer any questions you may have.

Biography of Dr. Donald Ian Macdonald

Professional Positions:

Dec. 1985 - Acting Assistant Secretary for Health

July 1984 - ADAMHA Administrator, Assistant Surgeon General, U.S. Public Health Service Commissioned Corps, U.S. Department of Health and Human Services

1962 - 1984 - General Pediatric Practice, Clearwater, Florida

1980 - 1984 - Clinical Associate Professor of Pediatrics, College of Medicine, University of South Florida, Tampa

Education:

Undergraduate - Williams College, Williamstown, Massachusetts, B.A., 1952

Graduate - Temple University School of Medicine, Philadelphia, Pennsylvania, M.D., 1958

Internship - Duval Medical Center, Jacksonville, Florida 1958 - 1959

Residency - Resident in Pediatrics, St. Christopher's Hospital for Children, Philadelphia, Pennsylvania 1959 - 1962
Chief Resident, 1961 - 1962

Certified:

American Board of Pediatrics, 1963

Fellow:

American Academy of Pediatrics, 1963 - Present

Personal:

Birth: April 15, 1931; New York, N.Y.
Family: Married, 4 children

INTRODUCTION OF ASSOCIATES

Dr. MACDONALD. With me this morning, Senator Weicker, are Mr. Forbush, Deputy Assistant Secretary for Health Operations, and our Budget Officer, Mr. Little. Behind me is a cast of people who I will introduce as need be.

OPENING REMARKS

The few comments I have this morning are very general. Our 1987 budget comes in three parts: One is the Public Health Service [PHS] management appropriation of $110.1 million; the second is $91.3 million, which is for commissioned officers retirement pay and medical benefits; the third is the $203.5 million proposed for the consolidated AIDS budget in the Office of the Assistant Secretary, which is a new request.

In the PHS management appropriation, which has a number of programs under the direct supervision of the Assistant Secretary for Health, there is a proposed increase of $10.3 million. All of our accounts, in fact, show an increase in 1987 over the presequestration 1986 budget. The $10.3 million in the PHS management appropriation, includes $5.8 million for program increases, and $4.5 million for restoration of funds sequestered in 1986.

Those increases are found in three areas. The National Center for Health Services Research, is requesting a $3 million increase to do the national medical expenditure survey. The National Center for Health Statistics has asked for an increase to get ready for the upcoming health and nutrition examination survey proposed for 1988. The remainder of the increase will restore funds sequestered in 1986.

In the "Retirement pay and medical benefits" account, which is an entitlement account, we have asked for an increase of $10.5 million.

For AIDS, which may interest you more than the other budget areas, I have with me Dr. Walter Dowdle, who has been appointed as the AIDS coordinator in the Office of the Assistant Secretary. Dr. Tony Fauci, who is the NIH AIDS coordinator, is with us also.

The request for AIDS of $203 million does not include the $9.8 million that the Food and Drug Administration is requesting from another committee. The purposes of the consolidation are many, but we feel that it does give us better ability to coordinate, more flexibility, and a chance to enhance future planning for this disease, which the Department considers its No. 1 health problem.

With that, I will say that we will all be pleased to answer your questions.

CENTRALIZATION OF AIDS FUNDING

Senator WEICKER. I am concerned, very frankly, over the centralization of the AIDS money in your office. I really want to discuss that in some detail this morning. I don't think there is any question of the fact that there has to be a coordination effort, nobody is denying that.

I worry about raising this to another level of bureaucracy rather than to have the various Institute heads be able to make their judgments when it comes to research. Maybe that would be a good point on which to start off the dialog here.

Dr. MACDONALD. From a personal standpoint, when I was appointed Acting Assistant Secretary for Health in December, it was obvious to me in talking to my predecessors, Dr. Mason and Dr. Brandt, that involvement of the Assistant Secretary for Health with the AIDS issues was growing to a point where it was a full-time job in itself.

Dr. Brandt became involved early and increased his time. Dr. Mason was spending almost one-half of his time on AIDS. From a personal standpoint, there was a need within the Office of the Assistant Secretary for Health for somebody who could devote more time tying things together. For that reason, Dr. Dowdle has been assigned to the Assistant Secretary on detail from the Centers for Disease Control [CDC].

I think, in honesty, that Dr. Dowdle is working so well that the CDC, NIH, and the Institute directors feel very comfortable with him as the coordinator, and not the director of their programs.

What I am saying is that I think that the centralization concept does have merit. In a management sense, it does give us flexibility.

What we plan for the 1987 budget is really no change from the 1986 money in terms of general direction. When we get into 1988 planning, I think that it will really help to have a strong focal point.

Senator WEICKER. But if I were an Institute director, it would seem to me that if targets of opportunity open up that I would move on to those a lot faster than I could if I had to go to the Director of NIH, and then on to your office, and then down to Dr. Dowdle. There has to be something lost in the flexibility.

Dr. MACDONALD. I would think that there is more flexibility if it is not all specifically identified by line item at the beginning. For example, Dr. Fauci may say that we need to proceed with more drug trials because of what we have learned in our early drug trials. Rather than coming back for a separate supplemental through the regular budget process, discussions with people from the National Cancer Institute, CDC, and the Alcohol, Drug Abuse, and Mental Health Administration [ADAMHA] could lead to a decision being made at the PHS level to redirect funds. I think that this approach gives us more flexibility than what you are saying.

Senator WEICKER. However, don't the various requests for AIDS money from the Institutes have to compete with the other demands upon your particular budget?

Dr. MACDONALD. I think that they would compete within an overall AIDS budget.

Senator WEICKER. Not an overall AIDS budget, the overall budget under your control.

Dr. MACDONALD. There is a provision in the appropriation language which will allow up to 1 percent of appropriated PHS funds to be transferred to supplement the AIDS account, without coming back to

you. That is an additional $86.8 million which will be available to the AIDS fund if that is the direction that we feel we need to pursue.

Senator WEICKER. In the past, as the need arose for additional AIDS funding, the Department has asked the Congress to permit a reprogramming of funds from other activities, or the Institute could shift small amounts of money into the AIDS research effort.

Under the consolidation proposal, would you still request a reprogramming, or would you simply eliminate such activities as the hotlines, and the community demonstrations, in order to put additional funding into research without consulting the Congress?

Dr. MACDONALD. We are aware of your concern, and the concern of other Members of Congress, and we would not anticipate taking any action without consulting you. However, we would like the flexibility of being able to make program decisions without having to go through the reprogramming or supplemental budget process.

It would be much quicker if we were given permission, within our own consolidated budget, to make those shifts. We recognize the need to answer to you and others when those shifts are made.

I think that it is a general rule, and you know that from previous discussions, that categorical funding can be appropriate in many instances but the more flexibility an Institute director is given, the better able he is to respond to changing program needs.

CONCERNS REGARDING ADMINISTRATIVE OVERSIGHT

Senator WEICKER. You know what my problem is, and I don't want this in any way to reflect upon you or your position, but my problem is simply this: There couldn't be a better juxtaposition, you and the previous witness. I am having this conversation with you, and I have great respect for you, Dr. Macdonald. But this is a great juxtaposition, and this is one of the problems I have.

No matter what the philosophies of this administration are, I don't worry that work goes on at the Institute level, I really don't. I don't worry, in other words, that the philosophy is going to invade Dr. Fauci, or Dr. Lenfant, or Dr. Löe one way or the other, they are scientists and they are men of medicine, they are going to do their job. I might say that the same holds true with Dr. Wyngaarden. I don't worry about that.

I worry, though, when we start putting the controls in the hands of under secretaries and assistant secretaries around here, all of a sudden we have a sort of philosophical bent to what it is that we do. Nothing could make that clearer than the previous testimony here, when it comes to community health centers, and HEAL loans, and all the rest.

Believe me, that man, Kelso, didn't believe in anything that he was to be the advocate for. He was driven by the budget, period, regardless of what his own facts said. That is a heck of a thing for a scientist, or a person of medicine. This is what we are going to do, never mind the facts.

I worry as this control, in other words, comes out of the Institutes, out of the National Institutes of Health, into a Secretary's office, that the philosophy all of a sudden is going to dominate, rather than the needs of medicine, just as I indicated the needs of the underprivileged youngsters desiring to go to medical school, or the needs of the poor populations in terms of community health centers, or the needs of the nurses, et cetera.

As I said, I don't want this to be a reflection on you because I want to make it clear, and I repeat it again, my respect for you. But if you are gone, and all of a sudden we are going to get some Heritage Foundation type walking into the position, out goes medicine, out goes science, out go the needs. I get very uncomfortable with that.

I don't know who, I can assure you right now, in the National Institutes of Health, the directors, I don't know who is a Republican, or who is a Democrat, who is conservative, and who is liberal, and I don't care as long as they do their job as men and women of science. That is all I care about. That is all I care about.

That is what this apprehension is as to the centralization, which I normally wouldn't think about, but I have seen this so misused in so many instances under the aegis of this committee that it really is a concern of mine, and in so doing, possibly stifling the creativity and the ability to find a solution to our problems that comes with a total freedom of thought which I find to be somewhat limited in the view of this administration.

Dr. MACDONALD. I understand what you are saying, and I would just respond by saying that the present system of Institutes submitting budgets to agencies, and agencies submitting budgets to the Public Health Service has the same constraints as the model you propose.

Senator WEICKER. Except that I am adding one more layer. Under the present circumstances, I agree, but we are adding one more layer as far as you are concerned.

Dr. MACDONALD. With the Public Health Service.

Senator WEICKER. It still has to go to the Public Health Service, and then it has to go to the Secretary, and to OMB, I grant you, but now it adds one more layer.

SUPPORT FROM THE ASSISTANT SECRETARY FOR HEALTH

Dr. MACDONALD. I have not been a long-term player in the Public Health Service, but I am aware of the history of Assistant Secretaries who have been health conscious, throughout the political changes in climate, and who also have a record of doing what they determine is in the best interest of the Public Health Service.

The men that you have mentioned work very well together with me, as they did with my predecessors, Jim Mason and Ed Brandt.

Senator WEICKER. It has been described to me that this system—I will try to remember the exact analogy—is very similar to a situation where, as a commanding officer in a military scenario, you send your troops to the front with their guns, and you say, when you get there, when you

see what the situation is, then you can call back for whatever number of bullets you need for those guns. That could be a rather disastrous affair before it is all over. Do you find that to be an accurate analogy or not?

Dr. MACDONALD. I think that that was more of an accurate analogy before Dr. Dowdle came on board. He is on the phone day to day with Dr. Fauci and Dr. DeVita, and the other players. I think that we have done much to improve communication in the last 3 months.

I think that one of the major problems with AIDS is the public conception of no centralized leadership, and that is going to change as the public sees a more coordinated plan in appropriation requests and in management.

Senator WEICKER. Would you like to have Dr. Dowdle have a few words to say on this subject.

Dr. MACDONALD. I would always like Dr. Dowdle to have the opportunity to speak.

Senator WEICKER. I would like to welcome him to the committee.

Dr. DOWDLE. Thank you.

Senator WEICKER. Please feel free to just generally comment. You have been here, and you have been listening to this back and forth, now if you would like to add your comments to it.

COORDINATION OF ACTIVITIES

Dr. DOWDLE. There is one element that I would like to bring in here, and that is intensive use of the PHS AIDS executive task force, which was begun by Dr. Brandt nearly 2 years ago. It has functioned very, very well, in representing all of the PHS agencies that are involved in AIDS.

The task force meets every 2 weeks. There are subgroups on various subjects. The task force discusses at considerable length what has been done in AIDS, and what needs to be done, and develops the broad plan to meet those needs.

We are, in fact, in the process of reviewing the PHS plan that was published in September. The task force provides a way in which we can communicate, and a way in which we can develop plans together. So AIDS planning is not done in a vacuum in the sense that it might be done by one or two individuals in the Assistant Secretary's Office, but rather planning is done through a collegial group working together.

The task force provides some of the safeguards that you may be concerned about.

Senator WEICKER. How do you find your experience with the various parties involved in this AIDS effort? Do you find that this is a smooth relationship in terms of getting the money to them?

Dr. DOWDLE. I might say, at this point, we haven't been faced with the need to apportion funds except for a few issues regarding the 1987 budget. But essentially, right now, the 1987 budget proposal is fixed, therefore, the intent is to provide those funds as planned.

I think as far as 1987 goes, any changes that might be made in that budget would require first a review as to whether or not we are proceeding according to plan and as to whether or not accomplishments dictate any changes in the plan. Any adjustments will be made with everyone participating in the recommendations.

POSSIBLE BUDGET CONSTRAINTS

Senator WEICKER. Let me ask you this question. Are you constrained by any budgetary considerations in this particular situation, the AIDS situation, the AIDS fight? Do you feel constrained at all by the budgetary considerations?

Dr. DOWDLE. We have to work within the framework of the budget that we are given, but at the same time, if additional needs are identified, these will be brought to the attention of the Assistant Secretary, through the task force or through individual agencies.

Senator WEICKER. All I am saying is, are you here to defend the budget, or are you here to do whatever is necessary to get on top of this, probably the most serious medical problem that we have ever faced in our lifetime?

Dr. DOWDLE. The primary purpose, of course, is to do whatever we can to resolve the AIDS problem.

Senator WEICKER. Senator Harkin.

Senator HARKIN. Mr. Chairman, I don't have any questions on this specific topic, but I do have something that I would like to cover with Dr. Macdonald.

Senator WEICKER. Go ahead and move on with Dr. Macdonald. If I have further questions, I will ask them later. You go ahead.

Senator HARKIN. I did not want to interrupt the AIDS discussion.

Senator WEICKER. You go right ahead, you have been very patient.

USER LIAISON PROGRAM

Senator HARKIN. Dr. Macdonald, I have been contacted by a number of people from the State of Iowa, the Lieutenant Governor and State senators, who work on the health committees of the Iowa Legislature, about doing away with the user liaison programs.

I read your testimony, and I note that you devoted about three sentences to it on page 3. You said that it will be continued as an inhouse effort to broker information between State and local officials and health services research centers in the States.

I am rather curious as to what happened last week with this program. Last Friday, my staff tried but was unable to contact the Department to ask that transfers out of the user liaison personnel be postponed until this subcommittee had the opportunity to determine whether the program's contract activity should be eliminated as you have proposed, or continued in its present structure as the subcommittee has recommended in the past. In the fiscal year 1986 report, we recommended that it be continued.

I also know that there are at least two other Senators, besides myself, who are interested in this program. It seemed odd to me, after talking with my staff and finding out what happened last Friday, that such precipitous action was taken on Friday to get rid of, I suppose I should say, to transfer I don't know how many individuals it was, six or seven, out of the User Liaison Program on 1 day's notice.

On just 1 day's notice, they were transferred out, especially when you were going to be up here today. I think there was enough communication back and forth from my staff, and from other people, that we were interested in talking with you about this program.

We wanted to request last Friday that these transfers be delayed until after we had a chance to go over this with you, but it looks like we are presented with a fait accompli, it was done, and it is over with.

I guess I would like to know what is the current status of the User Liaison Program, and how do you intend to carry out this inhouse effort to broker this information if you don't have any personnel there.

Dr. MACDONALD. Senator, I apologize for not getting back to your staff, if I was supposed to. I did speak with a member of Senator Weicker's staff. If your calls were not returned, I apologize.

Obviously, the Congress has a right to information about the changes which have been made. Certainly, we are not talking about transferring people who can't be recalled or put back.

The User Liaison Program is a part of an effort to disseminate information from the National Center for Health Services Research, and we are mandated to spend either 10 percent of their research budget or $1.5 million a year for three functions, one of which is the User Liaison Program.

Another of those three responsibilities is to provide technical assistance to States. The third function is dissemination activities. We anticipate that we will spend approximately $1.6 million this year on those three functions.

It was planned that the User Liaison Program would be restructured, and the sequestration accelerated that, but in truth we were not planning on operating that program in the same way as we had previously. In the 1987 budget, our spending plan has gone from $1.2 million in 1985 down to $175,000.

The concern was that we didn't think that we were getting, in terms of priority, what we were paying for. Sixty percent of the User Liaison Program is for transportation and per diem, and for contractor support to bring in State people for knowledge transfer.

Senator HARKIN. Transportation, and what else?

Dr. MACDONALD. Per diem, housing, and related costs, and for the contractor overhead on that. What is obvious to us is that there may be other ways to accomplish this. In 28 States, there are 35 centers that are qualified to disseminate that information. It is our feeling that instead of organizing workshops, we would work more strongly on promoting local dissemination.

Again, I apologize about the timing, but in truth, John Marshall, the Director of the Center—who may want to respond to this also—has notified at least some Senate staff of his intent to do this well before last week.

STAFF REASSIGNMENTS AND PROGRAM COSTS

Dr. MARSHALL. I would be pleased to add to that, if I may.

The individuals who were detailed to other positions within the National Center, were actually two clerical positions and one administrative assistant, and one professional person. That will leave the User Liaison Program with two professionals and one clerical person to carry out the restructured activities that I intend them to develop.

The director of the program had been informed over 2 weeks earlier that I intended to reassign some staff people. He asked me for some time to present me with an alternative. He didn't. I notified him on Thursday that if he didn't do that by Friday, I would go ahead with my plan. He had asked me not to talk to the staff about the reassignment.

They have been reassigned, but none of them have been moved more than 200 feet away from the desk that they were occupying. So it is not as if they have been terminated, or anything of that sort.

Second, the cost of the contract, Dr. Macdonald has alluded to that in general terms, the last workshop that this program put on, which was attended by 26 State legislators, or members of the executive branch in the State, cost $168,000.

Senator HARKIN. Did you say that it was attended by 26 States?

Dr. MARSHALL. Twenty-six individuals were there.

Senator HARKIN. From that many States?

Dr. MARSHALL. No; there were probably about 12 States represented, but I am not absolutely sure of that number. I will provide that for the record.

Senator HARKIN. Why don't you do so.

[The information follows:]

The use of health services research by State and local government officials, Rensselaerville, NY, October 20–26, 1986

[26 participants representing 17 States]

State	No. of participants	State	No. of participants
California	2	New Jersey	1
Colorado	1	Oregon	1
Connecticut	3	Tennessee	1
Hawaii	3	Texas	1
Iowa	3	Utah	2
Kentucky	1	Vermont	1
Maine	2	Washington	1
Minnesota	1	West Virginia	1
New Hampshire	1		

COST OF WORKSHOP PROGRAM

Dr. MARSHALL. It was held in Rensselaerville, NY. That came to something over $6,200 a person. We could have sent those individuals to Yale School of Public Health for a semester of training for that amount of money.

Senator HARKIN. How much did it cost?

Dr. MARSHALL. It cost $163,000 for 26 individuals.

Senator HARKIN. How long was it, 1 week?

Dr. MARSHALL. It was 4½ days, I think.

Senator HARKIN. That is for transportation.

Dr. MARSHALL. That is transportation, the cost of their lodging, their subsistence, and the fees for the contractor who organized the meeting.

Senator HARKIN. Who was the contractor because housing, food, and transportation can't come to $6,200 per person for 4 days. Who was the contractor?

Dr. MARSHALL. The contractor for that was Lewin Associates.

Senator HARKIN. Who did you say?

Dr. MARSHALL. An organization called Lewin Associates.

Senator HARKIN. So it was $163,000, 26 individuals, and it was held at Rensselaer Polytech?

Dr. MARSHALL. No; it was held at a retreat center in upstate New York, in Rensselaerville.

Senator HARKIN. Sixty-two hundred dollars per person, you fly them in, you put them up for 4 or 5 days, I can't imagine what this contractor could have done that would have cost that much.

Dr. MARSHALL. The contractor had personnel there. The contractor charged us for their time in preparing lectures that were presented to these individuals. The contractor brought in some consultants to speak to them.

Iowa happens to be one of the States in which there is a Health Services Research Center at the University of Iowa. I don't know whether anyone from Iowa was in attendance at this particular meeting, but it seems to me that we could have organized something in Iowa City for less money than that, or in Ames.

Senator HARKIN. I will be the first to admit that I am not intimately knowledgeable about this program. All I know is that I have been contacted by a number of people in Iowa who have related to me individually, and to my staff, that we have had in Iowa a really topnotch Medicaid Cost Containment Program and they say that they base it on the User Liaison Program.

We have developed health maintenance organizations [HMO's] in Iowa, again through this program. We have put in indigent care programs together, which they tell me was all based through this program. I have seen the effects of those in Iowa, and now I am concerned that this program is being done away with, when at least in Iowa we have seen some good stuff come out of it.

Dr. MARSHALL. I am always pleased to have the folks contribute good things to programs in the National Center for Health Services Research.

But this program only disseminates research findings that are developed by other people. It doesn't do the work itself.

Part of the dilemma in which I find myself, and I have described the center as resting on sort of a three-legged milking stool of internal research, investigator supported research in academic institutions, and disseminations. One has to constantly shift those priorities. If I spend less money for research, then there isn't anything to disseminate 1, 2, 3 years from now. I am simply trying to keep this in balance with the resources that I have.

I had concluded that the particular way of doing it was not as cost effective as it needed to be, and that I believe that we can develop an inhouse capability so that when one of the legislators from Iowa needs information about HMO's, we can put them in touch by telephone with the people who can give them information, who can point them to places in the literature. We do that throughout the National Center. We provide a lot of that kind of technical assistance.

It is just that this workshop idea has gotten to the point where it is too expensive. It is a luxury that we can no longer afford.

CONSTITUENT SUPPORT

Senator HARKIN. Dr. Marshall, what you say sounds reasonable to me. There are a couple of other things that I want to cover with you, though.

There is a letter signed by over 30 leading researchers which was sent to the chair of this committee, with copies sent to all of us, on February 27, urging the committee to support a restoration of funding for the User Liaison Program for this year and next year.

Again, they are taking the position that these 35 centers in 28 States can fulfill the information needs effectively well. How do you respond to this letter that was sent to the chair of the committee that 38 leading researchers said that they would like to see this program continue.

Dr. MARSHALL. Sir, I haven't seen the letter, nor am I aware of who the individuals are who have signed it. I have heard about the letter, and I have talked to a number of people that I consider to be leading researchers, and they tell me that they did not sign the letter, although many of them were approached to sign it.

I have seen a letter that was circulated by the San Diego Health Department to State and county health officers. I will say that it is not a letter that I would characterize as being an accurate portrayal of what the facts are. Again, this particular letter argues for the utility of health services research, and sort of creates the impression that this is because of the User Liaison Program, and not because the research had been done by other individuals, in many cases supported by our organization.

Senator HARKIN. Can you tell me what the Alpha Center is, or do you know who the Alpha Center is?

Dr. MARSHALL. Yes, sir; the Alpha Center is a contractor that has done some work for the National Center. It is basically an outgrowth of the health planning activity. They were funded under that originally as

one of three supposedly regional centers, one on the east coast, one in the Midwest, and one on the west coast, that support planning agencies.

Two years ago when we competed the contract for the User Liaison Program, the Alpha Center was one of the successful contractors.

WORKSHOP ON RURAL HEALTH

Senator HARKIN. I don't know that personally, but again the same people from Iowa said that several States, Kansas, Nebraska, Colorado, North Dakota, and Iowa, joined in an effort to get a workshop on rural health care issues. Evidently, it was scheduled to take place, and evidently the Alpha Center was the contractor that developed this workshop on rural health care.

Dr. MARSHALL. Yes, sir; that is correct.

Senator HARKIN. But I guess this is now going to be canceled because of this?

Dr. MARSHALL. I had said that we would not subsidize the travel. Some of the preliminary planning has been done, and if the individuals in those States would like to go ahead with the plan themselves, they certainly ought to do that. I know that the Alpha Center would be delighted to have that business because they are pinched by this turn in our program.

Senator HARKIN. I have not been contacted by the Alpha Center.

Dr. MARSHALL. I would not expect so.

Senator HARKIN. I was contacted by individuals in Iowa who had been active with other people in other States to set up this workshop on rural health care.

Dr. MARSHALL. That workshop was initially scheduled for last spring, and it was rescheduled for August, I believe, and it was canceled both times at the behest of people in the States, and deferred until fiscal year 1986.

Senator HARKIN. What you are saying is that if the States want to go ahead and have it, they will have to fund it themselves.

Dr. MARSHALL. Yes, sir; there was another workshop planned in the State of Michigan, and the Michigan Legislature decided that it would put up the $50,000 to go ahead and have that conference. So that one will be held.

RESTRUCTURING THE PROGRAM

Senator HARKIN. Mr. Chairman, thank you.

Again, one last thing, what you are going to do, you are going to keep three people on in the User Liaison Program to act as some kind of a clearinghouse or center for States to contact, to set up liaison with these other centers around the United States.

Dr. MARSHALL. Yes, sir.

Senator HARKIN. To try to disseminate that information.

Dr. MARSHALL. Yes, sir, and with the Intergovernmental Health Policy Program, which is operated out of George Washington University, with some Federal funding from other Federal agencies. They do a lot

of this kind of special publication and special seminar work for the States, except the States send their own people to that, rather than having it subsidized by the Federal Government.

Dr. MACDONALD. And Dr. Marshall anticipates that he will spend $1.6 million this year for technical assistance and dissemination activities. So it is not as if we are giving up on that, rather we are restructuring activities within the dissemination part of it.

Senator HARKIN. How much did you spend last year?

Dr. MARSHALL. Last year, we spent about $1 million, just shy of $1.2 million.

Senator HARKIN. You spent $1.2 million, and you put on all of these expensive workshops.

Dr. MARSHALL. Yes, sir.

Senator HARKIN. You are going to cancel all of these expensive workshops, take one-half the staff away, and you are going to spend $1.6 million?

Dr. MARSHALL. No, sir; that includes—your question to me was how much did I spend just on the User Liaison Program, not how much did I spend on the user liaison technical assistance, and dissemination.

Senator HARKIN. You are saying that you are going to spend less on user liaison, much less.

Dr. MARSHALL. Yes, sir.

Senator HARKIN. But you are going to keep the same for the technical assistance and the dissemination.

Dr. MARSHALL. That is correct.

Senator HARKIN. What you say sounds reasonable. As I said, I don't have any real knowledge of it, I just know that people in Iowa have been quite upset about this, and I wanted to get this on the record, and find out just what was happening.

Dr. MARSHALL. I appreciate your giving me an opportunity to explain what we are doing, Senator.

Senator HARKIN. Thank you, Mr. Chairman.

Senator WEICKER. Senator Specter.

BLACK INFANT MORTALITY

Senator Specter. Thank you, Mr. Chairman.

Dr. MacDonald, I have some questions which I would like to submit to you for the record, and I would like to make one supplemental statement about a specific problem in Pittsburgh on black infant mortality. It is very, very high, an alarming problem, really, nationwide, but for some reason it has struck in Pittsburgh with a greater intensity.

The questions which I am submitting for the record, which I would like to have your responses to, go to that issue. I would also appreciate it if you would take a look at some legislation which I have introduced on this subject, and give your response to it.

Thank you very much.

Thank you, Mr. Chairman.

Senator WEICKER. I would hope that you would submit those questions also to Mr. Kelso. It seems to me that he is the appropriate person, at least insofar as the community health centers are concerned. I really mean it, Senator, because I think it is a very valuable line of questioning. I am sure that Dr. Macdonald has his responses to it, but I think Mr. Kelso ought to have those questions posed to him for response to the record.

Senator SPECTER. I shall do that. I think your suggestion is a good one, Mr. Chairman.

NATIONAL CENTER FOR HEALTH STATISTICS

Senator WEICKER. All right, I have two questions on the National Center for Health Statistics.

In the last several years, we have seen a tremendous amount of change in the way medical care is being delivered—new group practice arrangements for physicians, more surgery, and other medical procedures being done outside of hospitals, et cetera.

Does the National Center have adequate data systems in place to tell us what these changes mean to the types of health care Americans are getting, and what the implications are for national health policy?

Dr. MACDONALD. I am going to ask Dr. Feinleib, the Director of the National Center, to answer that.

Dr. FEINLEIB. Thank you, Mr. Chairman.

The National Center for Health Statistics does have an extensive survey system to assess health care and health care facilities which consists of three parts.

The hospital discharge survey, which monitors the in-hospital discharges in the country; the national nursing home survey; and the national ambulatory medical care survey. These three surveys are active, but the ability to extend them to new forms of services, new modalities of treating people, has not progressed as rapidly as we would have liked it. In particular, the ambulatory medical care survey has been handicapped because it has been based on private physician practices, and it has not been able to extend into emergency rooms and other care facilities.

Within the available resources, we are covering the central features of the health care system.

Senator WEICKER. Relative to the vital statistics system, this information is rather basic as it relates to infant mortality, life expectancy, cause of death, and yet the States that provide the data to the National Center for Health Statistics say that the system is chronically underfunded and there is a real possibility that the continued viability of the system is in jeopardy. What do you say to that?

Dr. FEINLEIB. Right now the system is viable. We have recently completed all the State involvement with deaths and births, but the main problem here is that whereas in the late 1970's, we were able to fund approximately 40 percent of the State costs for establishing the statistical system, it has now fallen to about 26 percent for the Federal share of this.

The States have their problems in being able to maintain their funding levels for their part, and they are looking to the Federal sector to provide leadership in supporting the system, and in implementing new systems.

The most distressing thing is that when we have need for more data, including infant birth records, and occupational data, the States are reluctant to get involved without having assurances of adequate levels of funding. So it is handicapping our ability to be able to keep up with the issues that I think are important.

Senator WEICKER. In other words, the concern that I detect is, maybe we can keep up with it now, but where are we going to be 5 years from now.

Dr. FEINLEIB. That is correct. I might point out that every 10 years, in connection with the census, we try to advise them to obtain new information. For example, in 1988, we will introduce a new certificate to be ready for the 1990 census, which will include a number of new items like Hispanic identifiers, medical condition of the mother at the time of birth, prenatal care; additional information on the death certificate involving conditions from multiple factors influencing death.

We would like to introduce all of these things, and provide the information that the country needs to understand these conditions. We just hope that we will have the resources to be able to do it.

INCREASED FUNDING FOR INFANT MORTALITY

Dr. MACDONALD. Senator, regarding infant mortality—which you suggested appropriately that Mr. Kelso may respond—it is important to point out that NIH is asking for increased funding this year to study infant mortality. Also, CDC is enhancing its efforts, and is asking for another $1.4 million. The National Center for Health Statistics is planning to spend $400,000 in 1987 to link birth records with death records of those infants that die in the first year of life.

Senator WEICKER. Dr. Macdonald, there is nothing mysterious to me about what is going on with infant mortality. To me, the statistics here, maybe they are not quite as accurate as they should be. What I find is that mainly in your urban areas, as it is my own State of Connecticut, in Hartford, prenatal care, obviously, is not getting across. Not only is the infant mortality statistic insofar as the urban areas are concerned a disgrace, but it is a disgrace if compared on an international basis, but it is also a disgrace if compared right here in the United States between the highly populated urban areas and the other portions of the country.

Again, let's assume the fact that you don't care about people's lives, we are just conscious of the budget, so let's start on a budget basis. The cost of the low birth weight baby compared to a healthy baby is staggering.

You go ahead and give me the community health centers, and you give me the money to fund those centers, and I will tell you that it will knock down both of those statistics.

Based on the President's 1987 budget proposal, community and migrant health centers, they would require them to drop more than 550,000 people from their rolls, 60 percent of these people are women and children. An equal number have no insurance alternative. For the 200,000 in rural areas, there are no alternative providers if their clinics close. That, in my opinion, anyway, is where the problem exists, and where money should be spent.

In any event, I don't know what Senator Specter's questions were, but I would hope that you would respond to them, as well as Mr. Kelso.

What I find hard to accept from Mr. Kelso, and you have not been in this area, is that in light of the statistics, we persist in making the budgetary choices that appear in this 1987 budget.

I don't know where these figures came from, but under this budget proposal, they say that 1,200 unnecessary deaths would occur, and 50 percent would be babies. That is information from community health centers, which I suppose have an interest in the matter, but if they are not on the mark, they certainly are, on the basis of past experience, trying to extrapolate some figures, which may have some value.

MINORITY HEALTH

Dr. MACDONALD. A part of Mr. Kelso's response will be that within the maternal and child health block, there is reprogramming of $2 million to go to infant mortality problems, to make it a total of $5 million in 1987.

I don't know where those numbers come from, but there is a change in our priority setting within the maternal and child health block grant, to focus on infant mortality.

One of the major issues that Senator Specter raises is the whole issue of minority health, and certainly infant mortality in New Haven and other places is clearly related to a problem that nobody has a very good grip on.

We are trying to get a better understanding of the problem. Secretary Bowen's first appointment when he came to HHS was to appoint Dr. Nickens, who is here with me, as the first Director of the Office of Minority Health. Dr. Nickens is charged with looking at these issues and, hopefully, next year we will have answers, or will be closer to having answers than we are now.

Senator WEICKER. Dr. Nickens, I welcome you also to your latest endeavor. I also would hope that within the next several months, you would pay a visit to Hartford, CT, where there is a very substantial problem when it comes to infant mortality, which was thoroughly documented in a series of articles in the leading newspaper up there.

I am ashamed that it is taking place in my own State, except that I also know that it is taking place around the country, in cities other than Hartford. If it is there, there is no reason why we should wait to apply ourselves to it. I commend the Secretary for appointing Dr. Nickens.

I also, Dr. Nickens, would appreciate your getting in on it, and we will give you every assistance that you ask for.

Are there any further questions of this witness?

Senator HARKIN. I just have one other thing that I wanted to cover.

Senator WEICKER. Senator Harkin.

ADOLESCENT FAMILY LIFE

Senator HARKIN. The program for the Adolescent Family Life Program. Who is in charge of that?

Dr. MACDONALD. Jo Ann Gasper is the Deputy Assistant Secretary for Population Affairs, and she is in charge of that program. With me today is her deputy, Jerry Bennett.

Senator HARKIN. I wonder if I could have my staff get in contact with him, and if I could be briefed on this program, that kind of thing. Would that be all right?

Dr. MACDONALD. Yes; of course.

Senator HARKIN. How old is this program?

Dr. MACDONALD. The first projects were funded in 1982.

Senator HARKIN. You have a request for $14.7 million to deal with the whole area of adolescent sexual activities, and teenage pregnancies, and developing approaches for comprehensive services, et cetera.

We all know from news programs, and all the things that we have been reading on teenage pregnancies, what is happening. I am just interested in what is happening in this area, and what approaches are being taken. I would like to have a good, indepth briefing.

Dr. MACDONALD. Part of the problem in briefing you on the program is that many of the demonstrations are 5-year projects, and they are only partly through the grant period. What they will present to you is preliminary data.

Mr. BENNETT. This is, as you pointed out, a $14 million program, and it, obviously, is not intended to be the Department's only response to this issue. The intention of the program is to sponsor model demonstrations around the country, and our goal is to have at least two sites in every State. It also supports research on causes and consequences of adolescent pregnancy.

The goals of the program are to emphasize primary prevention as a means of dealing with the problem. There have been arguments made that provision of contraceptive services alone is just not the answer to the problem. What we have to do is to get at the issue of why teenagers become sexually active early, and that is one of the primary emphases in these programs. Another is on adoption as an option for teenage parents.

The emphasis of the program is to sponsor different demonstrations around the country and to enable communities to come up with reasonable approaches to try to deal with the problem in cooperation with other Federal programs and other community resources many of which provide contraceptive services and also care services for teenagers who do become pregnant and do become parents.

Dr. MACDONALD. As Mr. Bennett said, one of Secretary Bowen's main concerns is in this area, and there is really a lot more involved in finding a solution.

The issue of infant mortality is clearly tied to the issue of teen pregnancy. There are lots and lots of issues within our Department and this is one that the Secretary has expressed his interest in.

Senator HARKIN. I just wanted to express my interest in this matter.

Thank you, Mr. Chairman.

SEXUALLY ACTIVE TEENAGERS

Senator WEICKER. Let me make one comment. I don't understand what kind of an answer you got. You said, "why teenagers become sexually active." I don't understand that, what are you talking about?

Mr. BENNETT. If you look at teens from 13 to 19, you see different rates of sexual activity, obviously increasing over age. If you look at all teens in ages 13 to 19, about one-half are sexually active. The other half are, for some reason or another, deciding that becoming sexually active as a teen is not a good idea.

What we are trying to focus on is what are some of the factors that cause teens to become sexually active early, and what are some of the things that——

Senator WEICKER. What are some of those factors?

Mr. BENNETT. Factors like supervision, the environment in terms of messages on television, and the family values system, in terms of relationship to cognitive information on sex practices. Is there some factor, as we believe, in the relationship to drug use, or alcohol use, a relationship to school failure? Those are the factors, I think, we are talking about.

ALLOCATION OF FUNDING FOR AIDS

Senator WEICKER. Let me ask another question, getting back to the AIDS situation. Do the Institute heads have at their disposal, under this system of centralization in your office, any small portion of discretionary funds, in other words, so that they can move about without getting involved in going through your operation, or is everything going through your operation?

Dr. MACDONALD. We have an Institute director here. Do you want to comment on your degree of comfort with the centralization?

Senator WEICKER. That is not really the question that I asked. The question I asked is, under this system, and I am trying to understand the system as it now is, does each Institute head, in other words, have to, for 10 dollars' worth of expenditures, go through your office if it relates to AIDS?

Dr. MACDONALD. No.

Mr. FORBUSH. Mr. Chairman, if I could say one thing about the technical or budget management of the consolidated account, if it were approved for 1987.

We would not keep the money in a vault, and require each Institute director to come and jump through three hoops to get a few dollars. We have a plan right now, and you can see it portrayed in our budget, at the beginning of the year, we would make dollar allocations to all of the participants in the program, and we would not hold the money back. We would not dole it out quarter by quarter or month by month. We would give them an annual allocation based upon the plan at that stage. Then, if there was some necessity to make some adjustments in those allocations later in the year, we would do so, generally on a collaborative basis through the AIDS executive task force, under Dr. Dowdle's general direction.

It is not as fearsome, as might be perceived.

Dr. MACDONALD. To be specific, we would tell Dr. Wyngaarden, at the beginning of fiscal year 1987, that the amount of $143 million would be available for NIH work on their various efforts.

Senator WEICKER. Do you feel, Dr. Dowdle, that under this system, you, in effect, have some sort of a veto mechanism over Lenfant, DeVita, Fauci?

They have to make judgments, and they have to make them daily—I am talking about AIDS now, and nothing else but AIDS—where do you enter that picture? Can you turn to one of these men and say, "I think you are going down the wrong road. I want you to do such and such?"

Dr. DOWDLE. No; I think, basically, those decisions will be made in advance. As Mr. Forbush has indicated, moneys would be committed in advance once a decision is made as to how they are to be allocated. But I don't see any involvement in the day-to-day activities in that sense.

AIDS is a very complicated problem with different agencies having different pieces of the pie: with NIH, drugs and vaccines, and basic research; with CDC, epidemiologic information and education types of programs. In order to provide some sort of balance, we need frequent review at the PHS task force level, and the ability to provide some balance through resources.

Senator WEICKER. Assuming that you get the $143 million for AIDS for fiscal year 1987, when would you see the allocation being made of that?

Mr. FORBUSH. At the very beginning of the fiscal year. If the appropriation is enacted before the fiscal year begins, we would notify the agencies before the fiscal year, to give people clear signals as to what would be available.

Senator WEICKER. I just want to make sure that in the race—let me say one thing to you. I think Dr. Macdonald is correct in one thing, and I remember that this came up during the appropriations conference, it is the politicians who were yelling for an AIDS czar. I don't think that this is something that I heard from the committee itself, and I am not laying it at your doorstep.

I want to make sure that we are not doing the wrong thing. This is the time right now to sift out the pros and cons. Nobody will deny the

coordinating function that ought to be there. I am glad that Dr. Dowdle is aboard, and I have no problem with that.

I am rather sensitive, as I said, to the scientific world, and the freedom that it likes to operate within.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

I have further questions for response to the record, otherwise that is it.

Dr. MACDONALD. Thank you, sir.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

REPROGRAMMING AIDS MONEY

Question. In the past, as the need arose for additional AIDS funding, the Department has asked the Congress to permit a reprogramming of funds from other activities or the Institute could shift small amounts of money into the AIDS research effort. Under the consolidation proposal, would you still request a reprogramming or, would you simply eliminate such activities as the Hot-line and the Community Demonstrations in order to put additional funding into research, without consulting the Congress?

Answer. We currently intend to operate the proposed consolidated AIDS account for FY 1987 in such a manner that reprogrammings would not be requested, as this would seem to defeat the purpose of the proposal which is to increase PHS's flexibility to manage the total AIDS effort and to be more responsive to shifts in research emphasis as they may occur. As you know, we have asked that $15.3 million for AIDS service delivery demonstration projects and approximately $2 million for an expanded AIDS hotline be rescinded in FY 1986. If our proposed rescission is rejected by Congress, these programs would be funded in FY 1986.

Question. Isn't this simply a method by which you could eliminate certain AIDS efforts which the Congress supports but which you don't?

Answer. No, the proposal is not an attempt to circumvent supporting efforts which the Congress supports. Rather, our proposal is designed to increase our flexibility to respond to changing priorities resulting from new opportunities including specific scientific breakthroughs in AIDS research and prevention. As for program eliminations, PHS would seek Congressional Appropriation Committee approval before eliminating any program for which specific funding was provided.

AIDS CENTRALIZATION/MESSAGE TO RESEARCH SCIENTISTS

Question. The research scientist depends a great deal on research funding stability. That is the reason NIH grants are awarded for 3 or more years. The Department of Health and Human Services has a recent history of shifting or reprogramming of funds for AIDS among the programs under its jurisdiction. The GAO called attention to this problem in its report last year. Control of the research funds several bureaucratic layers above the peer review system will send a signal that the usual reliability of NIH commitments may not be present in AIDS research. How do you think this message might affect the recruiting of additional experienced scientists to AIDS research?

Answer. In the relatively short time the AIDS crisis has been with us, we have fortunately seen a remarkable willingness on the part of a few experienced, knowledgable researchers to put aside other highly important work in order to join the battle against this disease. This process did not happen "over night," and we are still attempting to enlist other qualified scientists.

It is also expected that placing all AIDS research funds under more direct control of the Assistant Secretary for Health will demonstrate to the extramural community the high priority given to this research area. As a consequence, we would expect recruitment of scientists to be enhanced.

AIDS - CENTRALIZATION

Question. I understand the logic of coordinating the AIDS research, education, and study efforts under your office. However, I have some serious concerns that we should discuss. The AIDS research effort is on-going. Will there be a need to rejustify approved ongoing projects, and won't that use up a great deal of valuable time?

Answer. Ongoing AIDS projects should not be affected by the proposed new procedure. The PHS requests for 1986 and 1987 is sufficient to meet all on-going requirements.

Question. Will the agencies involved in AIDS work be placed in an adversarial position in competing for finite funds under your control?

Answer. We do not believe the agencies will be placed in an increased adversarial position. The FY 1987 request is the consolidation of the agencies' request for AIDS resources. We are currently planning to distribute the resources to the agencies consistent with the distribution presented in our 1987 budget request (i.e., $45,409,000 for CDC; $142,990,000 for NIH; $13,733,000 for ADAMHA; and $1,350,000 for OASH).

Question. What will happen to the priorities already established and in come cases begun in FY 1986?

Answer. PHS will continue to provide support to these AIDS research priorities established for FY 1986 and currently plan to continue those activities in FY 1987 unless new scientific breakthroughs and opportunities occur which make our current AIDS research plan outdated.

Question. Won't this centralization create additional bureaucratic layers between available funds and the research scientist?

Answer. No. The budget for these activities are currently reviewed and approved in the same manner. We are not creating an additional layer, but are simply adding a full-time PHS AIDS Coordinator to assist the Assistant Secreary for Health and the existing PHS AIDS Executive Task Force. Dr. Walter Dowdle has been appointed as the PHS AIDS Coordinator and will be devoting his full time and attention to the overall coordination of PHS AIDS activities. While some minor additional financial management paperwork will be created, we regard the benefits from better overall coordination and flexibility to be worth this.

GRAMM-RUDMAN-HOLLINGS IMPACT

Question. Please explain the specific impact of the Gramm-Rudman-Hollings reduction on every OASH program in 1986. Include a detailed explanation of every program that either took a greater or lesser cut than 4.3%, and include in your explanation the reasons for that difference.

Answer. All OASH programs were reduced 4.3% across the board to accommodate the Gramm-Rudman-Hollings reduction of $4.5 million. A number of programmatic and administrative actions have been taken. The impact by program are as follows:

Health Services Research will save $0.7 million through restructuring the User Liaison Program, reducing travel expenditures and reducing the cost of program planning, coordination and management.

Health Statistics will save $2.0 million through the adjustment of the contract period for the purchase of vital statistics data from the states and by reducing training, travel, and delaying plans to purchase new office equipment.

Adolescent Family Life - The dollar levels awarded to grantees will be reduced for a savings of $0.6 million. Grantees will be encouraged to streamline activities which will have a minimal impact on services.

Smoking and Health will delay until 1987 a project on the prevalence of cigarette use and the use of smokeless tobacco products among teenagers and adolescents for a savings of $0.2 million.

Disease Prevention and Health Promotion will reduce the scope and level of support for the national public education campaigns for a savings of $0.1 million.

Physical Fitness and Sports will delay the printing and distribution of publications and leadership training aids and materials on physical fitness for youth for a savings of $0.1 million.

Public Health Service Management - Several management actions for savings of $0.8 million will be taken in this activity. These include delays in filling vacancies, travel and training reductions, and the postponement until 1987 of planned equipment purchases.

NATIONAL MEDICAL EXPENDITURE SURVEY

Question. The Administration's FY 1987 budget proposal includes $3 million to initiate data collection activities for the next cycle of the National Medical Expenditure Survey (NMES). How long will it take to complete the data collection for this survey and how much will it cost?

Answer. We expect the first household data to be available early in 1988 with final data files anticipated by 1990.

The survey costs for FY 1986 are $2.5 million and $5.5 million in FY 1987. The total cost over the four year period of the survey and development of public use tapes will be $45.0 million. The NCHSR is working with other programs within the Department to arrange for partial financial support for the survey.

Question. Is the Administration prepared to provide continued support of this survey in future years to insure that it is successfully completed?

Answer. Yes, the Administration is prepared to provide continued support for this survey.

Question. Net of the $3 million for the NMES, it is proposed that in FY 1987, NCHSR and HCT's funding level is approximately the same as in FY 1986 with no increase for inflation. At this funding level, what types of basic health services research activities will the Center be able to support? What is the number of new grants that will be funded in FY 1987 as compared to previous year? Are there any significant research activities that will have to be delayed because of funding limitations?

Answer. The number of new grants funded in FY 87 is estimated to equal the 1986 level of $4,303,000.

TECHNOLOGY ASSESSMENT GRANTS

Question. What steps have you taken to implement the Committee's recommendation that priority be given to investigator-initiated grant applications that address technology assessment? How many applications for research support related to technology assessment were received in FY 1985, and FY 1986, and how many of such projects will be supported in FY 1987?

Answer. The NCHSR has circulated a statement of research issues in technology assessment to the academic community. A copy of the most recent version is submitted for the record. The Center received 36 applications in FY 1985 and to date, 39 for FY 1986. We could possibly receive more. The number which will be supported in FY 1987 cannot be predicted, as that number will depend upon the quantity and quality of peer reviewed applications received. We anticipate, however, that support will approximate $4.7 million. Of this amount $4 million is from NCHSR's direct appropriation.

February 1986

NCHSR Offers Grants for Research on Health Care Technology Assessment

The National Center for Health Services Research and Health Care Technology Assessment (NCHSR) encourages interested and qualified investigators to apply for grants to conduct research in the field of health care technology assessment.

This announcement describes the research program in general, identifies areas of particular interest to NCHSR at this time, summarizes application and review procedures, and includes the address and telephone number of staff members who can provide advice and assistance.

NCHSR supports and conducts research on specific health care technologies, methods to improve technology assessment, and ways to monitor and affect the introduction and use of health care technologies, under the authority of Public Law 98-551. The term "health care technology" includes drugs, devices, and procedures used in providing health services and the organizational and supportive systems through which health care is delivered. Issues for research include the appropriate use, effectiveness, and cost effectiveness of health care technologies, as well as their economic, legal, and ethical consequences.

Expanding health insurance coverage and a period of unparalleled technological innovation have resulted in improved access to health care and higher quality care. These significant gains in delivering health services over the past two decades have not been without cost, however. Total national health expenditures currently amount to more than 11 percent of the Gross National Product. More than 40 percent of these expenditures are reimbursed through Medicare, Medicaid and other public programs (1). Third-party payors in the private sector, as well as individual purchasers of health services, share the same concerns for controlling costs while protecting or enhancing the quality of care. In the face of these pressures, even those technologies which do not seem to increase costs must be evaluated in terms of benefits to be gained and risks incurred by individual patients.

There are important cost and benefit questions from the societal viewpoint, as well as an array of ethical and legal concerns. Organ transplants, either live or artificial, represent a particularly poignant example of such problems, involving high costs, individual patient rights and expectations, societal needs and responsibilities, quality of life issues, and a host of related factors which need further exploration.

Long-term effects of technology utilization also deserve study in light of the untoward consequences which may not be recognizable early, the expanded applications of a technology beyond the conditions for which it was originally evaluated, and the evolution or displacement of a technology in medical practice. Furthermore, many technologies in common use have never been rigorously evaluated, and it has been suggested that as many as 15 to 20 percent of them may be useless, redundant or potentially dangerous (2). Because careful and sytematic investigations can make significant contributions to clarifying and resolving such problems, NCHSR intends to increase its activities in the field of technology assessment research considerably over the next few years.

Areas of research interest

Specific technologies: The reasons for selecting a particular technology to be evaluated must be justified in terms of representativeness, expected clinical or societal effects, or impact on the organization or financing of health services. Furthermore, NCHSR is particularly interested in those technologies that have reached a state of development in which questions can be asked about their effectiveness and appropriate use, rather than their safety and efficacy. (In this context, "effectiveness" refers to how well the technology works in actual clinical practice, rather than under research conditions.) Determinations of the safety and efficacy of many drugs and devices are largely the responsibility of other Federal agencies, including the National Institutes of Health and the Food and Drug Administration.

An important aspect of technology assessment consists of studies which systematically examine the organizational, economic, and clinical effects on the health care delivery system of introducing, modifying, or extending a specific technology. These policy studies place special emphasis on those unintended, indirect, or delayed consequences that affect the cost, accessibility and quality of health care available to the population. The effects of changes in the ways a technology is used are a matter of particular concern.

Other questions of interest include: comparative studies of diagnostic and therapeutic technologies in tertiary care centers *versus* community hospitals, evaluations of the validity and acceptability of the criteria in common use for determining the success or failure of medical technologies, studies of the interaction between newly introduced technologies and older technologies, and exploratory studies of the ability of providers and patients to understand and assess complex health care technologies.

Computer-based information systems are particularly important to NCHSR's technology assessment activities. The use of these systems for management and record-keeping purposes is expanding rapidly, providing greater opportunities for monitoring and exploring the effectiveness of changes in the use of diagnostic, therapeutic or supportive technologies. Systematic and comprehensive evaluations are needed of the role of artificial-intelligence techniques as decision aids in promoting more efficient and effective patient care. It is important to examine the value of clinical data bases in assessing technologies, and to explore the extent to which expanded and integrated practice-based and community-based information systems can serve as epidemiologic tools for technology assessment.

Methods for assessing technology: Currently the field of health care technology assessment is severely limited by methodologic and data problems which affect the accuracy, timeliness, and utility of evaluative information. Research in this category should focus on those methodologies with potential for broad application in a variety of health care settings or to a variety of technologies (3).

Cost-benefit and cost-effectiveness analysis techniques have become increasingly prominent in health policy discussions over the past few years (4),

but it is now being recognized that these methods, derived from studies of industry, cannot be safely applied to health issues without considerable modification, particularly with regard to concepts such as equity, quality of life, and society's responsibilities for health care. Similarly, decision analysis approaches seem promising for evaluating the effectiveness and efficiency of drugs, devices, and procedures (5), but considerable work is needed in such areas as assuring the accuracy and representativeness of data, or formulating simpler methods to assess values and probabilities.

Another method, meta-analysis, is a quantitative approach that estimates the effects of an experimental intervention through aggregating the results of a series of related studies (6). This technique offers great promise particularly for those technology assessment issues in which large-scale controlled trials are difficult to manage, prohibitively expensive, or hampered by serious ethical issues. Much more testing of the procedures used in this approach is needed, however, before meta-analysis can be considered valid and useful.

Another area in which methodologic investigation is important is the formulation of a persuasive strategy for selecting a particular technology to be assessed and identifying the stage in its development at which the evaluation would be most acceptable, economical, and useful. The widespread interest in evaluating technologies in all sectors of the health system is evident in the considerable number of organizations conducting technology assessment activities during the past few years, largely independent of each other (3). It would be of great value to establish a rational framework for coordinating and integrating these efforts.

Other examples of methodologic studies needed include the development of methods to assess the costs and benefits of rapidly changing technologies, short-term outcome measures to evaluate diagnostic and therapeutic effectiveness, innovative ways to use existing data sets for technology assessment, and improved techniques for eliciting and aggregating judgments and preferences.

Technology diffusion: Factors affecting the diffusion and adoption of technologies in the health care system are not well understood; it is important to learn more about how different incentives drive or impede the entire process. Such information is required for the rational allocation of scarce resources, the controlled development of useful technologies, and the restriction of questionable technologies. In addition, better information is required to determine the relative influence of factors which stimulate the genesis of a technology and contribute to its continued development and eventual application. Included among these factors are the likelihood of clinical advances, the potential for improved cost effectiveness, the profit motive in private organizations and the regulatory or protective concerns of public bodies, reimbursement policies, the influence of special interest groups, the threat of malpractice suits, and the management of life-threatening situations.

The use of technologies can be increased or restricted in a number of ways (regulatory efforts, reimbursement policies, educational or licensing restrictions, professional or lay promotional campaigns, etc.) and it would be useful to know which of these approaches are more effective, whether their effectiveness varies significantly with the technology or the target audience, and which methods are most appropriately used or encouraged by governmental agencies, directly or indirectly, in meeting their responsibilities.

Application and review procedures

The NCHSR extramural research program provides grant support for health care technology assessment, and is authorized by Section 305 of the Public Health Service Act (42 USC 242c), as amended by P.L. 98-551. Grants will be administered under the *Code of Federal Regulations*, 42 *CFR* Part 67, and the *Public Health Service Grants Policy Statement*.

Applications may be submitted by any public or private nonprofit institution or unit of State or local government. Applications must be submitted on Public Health Service form 398, Grant Application, except for applications from State and local governments, which are required to submit Standard Form 424, Application for Federal Assistance (Nonconstruction Programs).

Application materials are available from:

Chief, Review and Advisory Services Program
National Center for Health Services Research
and Health Care Technology Assessment
1-52 Park Building
Rockville, MD 20857; 301/443-3091

Application materials may be available from business or grants and contracts offices of academic or research institutions, and can be obtained from the National Institutes of Health, Division of Research Grants, whose address appears below. Enter "NCHSR" in item 2 on the front page of the Form 398.

The submission and review schedule is:

NIH/DRG submission	Study section review	Council review	Earliest start date
June 1	October	February	March 1
October 1	March	June	July 1
February 1	June	September	September 30

The original and 6 copies of the application should be sent or delivered to:

National Institutes of Health
Division of Research Grants
Room 240, Westwood Building
533 Westbard Avenue
Bethesda, MD 20205

All NCHSR research grant applications are reviewed for scientific and technical merit by a review panel of non-Federal scientists. Each application will be reviewed by the appropriate NCHSR study section according to the following criteria:

- the significance and originality of the project from a scientific and technical viewpoint
- the adequacy of the methodology proposed to carry out the project
- the availability of data and the adequacy of the data collection plan
- the appropriateness of the work plan and schedule for organizing and completing the project
- the qualifications of the principal investigator(s) and staff
- the adequacy of the facilities available to carry out the project
- the reasonableness of the budget

• the adequacy of the proposed protection of human and animal subjects.

Technology assessment applications exceeding $50,000 in direct costs require consultation with the National Advisory Council on Health Care Technology Assessment before funding decisions are made.

Potential applicants are encouraged to consult informally with NCHSR staff before submission of research grant applications. Additional information concerning this program announcement is available from those listed below by calling 301/443-2080.

Medical informatics: Gerald S. Cohen
Technology assessments of drugs and devices: James Ullom
Technology assessments of medical organizations: Richard DuBois, Ph.D.
Technology assessments of medical practices: James Calvert, M.D.
Development of methods and technology dissemination: James McAilister

Inquiries may be directed to:

National Center for Health Services Research
and Health Care Technology Assessment
Division of Extramural Research
Health Information Systems and Technology
Assessment
3-18 Park Building
Rockville, MD 20857

References

1. U.S. House of Representatives, Committee on Energy and Commerce. *Report on Medical Technology Assessment*. Report 98-818, 1984.

2. Iglehart, J.K. Health policy report: Another chance for technology assessment. *N Engl J Med* 309: 509-512, 1983.

3. National Academy of Sciences, Institute of Medicine. *Assessing Medical Technologies*. Washington, D.C., 1985.

4. U.S. Congress, Office of Technology Assessment. *The Implications of Cost-Effectiveness Analysis of Medical Technology: Summary*. U.S. Government Printing Office, 1980.

5. Weinstein, M.C., H.V. Fineberg. *Clinical Decision Analysis*. W.B. Saunders, Philadelphia, PA, 1980.

6. *Evaluation Studies Review Annual*, vol 8. R.J. Light, editor. Sage Publications, Beverly Hills, CA, 1983.

The NCHSR grant program is described in *Catalog of Federal Domestic Assistance* as Number 13.226. The review requirements of Executive Order 12372 are not applicable to NCHSR grant programs.

CLINICAL TRIALS VS PROSPECTIVE PAYMENT

Question. Clinical trials are one of the most valuable ways to bring the advances of scientific research to the bedside, and also to test the efficacy of older treatment modalities. I have heard some concern that the new prospective payment system (DRGs or Diagnostic Related Groups) used by Medicare is having an effect on these clinical trials. Have you looked into this, and if so, what are your findings?

Answer. NCHSR has received funds from the National Cancer Institute (NCI) and the Department and has committed some of its own resources to addressing this question. In collaboration with the NCI, we are assembling a unique data base, representative of hospitals treating cancer patients under experimental protocols compared against costs for patients not being treated under protocols. This data base should be assembled by early winter 1986, permitting our first analyses of the issue by late winter.

PURCHASE OF NON-PROFIT HOSPITALS

Question. The purchase of non-profit hospitals by health care corporations is a growing trend. Usually someone tries to make the case that these privately run hospitals can operate more efficiently and therefore at lower cost. Have you reviewed this claim, and what have you learned?

Answer. NCHSR-supported research has tracked a number of fast-paced developments in our health care system. Some of these are multihospital systems (MHS), preferred provider organizations,

for-profit HMO's, and freestanding emergency centers. The work related to what are referred to as (MHS) reveals that:

- o System hospitals have higher costs, primarily due to higher mark-ups on ancilliary services.

- o There appears to be little difference between MHS and independent hospitals in terms of access to care and quality of care.

- o The major advantage of system hospitals is their enhanced ability to operate in the capital markets.

MEDICAL MALPRACTICE

Question. A great deal of concern has been expressed about the "crisis" in medical malpractice. I don't believe that the question of professional liability lies within your purview, but is there some health policy implication that ought to be addressed?

Answer. Yes, there are several. These include:

- o Comparative analysis of recent state medical malpractice laws and amendments, including multivariate analysis of the effect of the tort law and other factors on the relative incidence of claims, size of malpractice claims, and on the process and level of settlement.

- o Analysis of the effects of the increase in medical malpractice premiums, claims, and settlements on the cost, delivery, and mix of medical services.

- o Systems analysis of the insurance industry with emphasis on the understanding of secular trends in the economics of establishing medical malpractice premiums.

- o Study of the relationship between trends in malpractice liability and negligent injury -- how viable is the "deterrant effect?"

- o Small-area analysis of the relationship between variations in medical practice, intervention to change standards of care, and the extent and nature of malpractice claims.

Question. What should you be doing in this area and what funding would be needed to address this issue?

Answer. Our proposed medical malpractice research agenda is:

- o Analysis of how new economic incentives (DRG payments to hospitals and greater use of capitation payments) affect the use of "defensive medicine."

- o Evaluation of hospital efforts and quality insurance and risk management and their relationship to claims and awards.

- o Small-area analysis of the relationship between variations in medical practice, intervention to change standards of care, and the extent and nature of malpractice claims.

- o Analysis of the problems and possible solutions associated with extending malpractice insurance to non-physician health care providers.

- o Comparative analysis of state medical malpractice laws, including multivariate analysis of the effect of changes in tort law and other factors on the relative incidence of

  claims, the size of malpractice claims, and on the process and level of settlement.

- o Analysis of the effects of the increase in medical malpractice premiums, claims, and settlements on the cost, delivery, and mix of medical services.

- o To what extent does the DRG system of hospital finance and capitation payment help to "distinguish defensive medicine from the over-utilization that results from economic incentives inherent in fee-for-service medicine?"

USER LIAISON PROGRAM

Question. Dr. Marshall, I have had a significant number of inquiries from other Senate members concerning your distribution of the FY 1986 Gramm-Rudman 4.3% budget reduction and the User Liaison Program. Please describe how the User Liaison Program has been affected by the 4.3% reduction, and why did you decide to distribute the cut in this fashion?

Answer. As a result of the reduction, the User Liaison Program has been restructured, reducing travel expenditures and reducing the cost of progam planning, coordination and management.

The User Liaison Program (ULP) currently operates largely through contractor support for meetings to disseminate and discuss health services research as well as for provision of technical assistance to State and local governments. Sixty percent of the ULP funds are expended on travel and subsistence for individuals from state governments attending these workshops and for support and contractor overhead.

The ULP is being restructured to provide greater reliance on local rather than Federal sources. State and local personnel will be referred to research centers most geographically convenient to their area. There are 35 health services research centers in 28 states. Federal staff will continue to provide brokering services and technical assistance in lieu of directly sponsoring workshops.

The reduction in FY 1986 funding for the ULP does exceed the 4.3% imposed on domestic programs for the second half of FY 86. Faced with the choice between an across the board reduction of 4.3% for all NCHSR activities, regardless of their priority, or restructuring of a program to enhance cost effectiveness, NCHSR selected the more responsible option.

Question. Has the User Liaison Program produced any measurable results in cost containment for health care?

Answer. The User Liaison Program has provided information and

other technical assistance to State and local officials on health care cost containment, but we have no evidence on how this specific information has been used by the assisted officials and translated into action at the State and local levels.

NATIONAL MEDICAL EXPENDITURE SURVEY

Question. Please give us a brief description of the National Medical Expenditure Study and tell how the results of this study may impact on the cost of medical care.

Answer. One way to answer that question is to look at the usefulness of the last survey that we did. It was conducted ten years ago but is still the best available source of information for some of the questions that are being asked. For example, when the issue of means testing for VA benefits was raised, we received requests for help from three different places (OMB, the Veterans Affairs Committee, and CBO) within the space of a few hours. We have made all kinds of estimates involving health insurance--estimates of catastrophic insurance, of the uninsured and inadequately insured, of the relationship between unemployment and insurance coverage, of the effects of a tax cap on employer-paid premiums. Data concerning the poor who do not qualify for Medicaid and the out-of-pocket expenses of the elderly on Medicare have been presented in testimony here on the Hill or appeared in Committee reports and the analyses of CBO. We regularly receive hundreds of requests each month from health administrators, state agencies, employee benefit specialists, and other health analysts around the country for published reports from the 1977 survey. Understand that we don't just collect the data and wait for someone else to use it. We are a research agency, and we are in the business of answering the questions that policymakers have.

We expect the 1987 survey to be even more useful, the data base for addressing the policy issues of the 1990's. We have broadened the scope to include institutionalized persons and expenditures, while concentrating the sample somewhat on the aged and functionally impaired. In this way we will be better able to address the issues raised by the increasing proportion of elderly Americans, the rapid growth of Medicaid expenditures for care provided in nursing homes and the facilities for the mentally retarded, and the public and private burdens of long-term care. This survey will, for example, provide an opportunity to update HCFA's Medicare capitation rate for HMOs (the AAAPCC or Average Adjusted Area Per Capita Cost) for the first time since the Current Medicare Survey was discontinued in the 1970's. We are also helping the Indian Health Service to collect data on the health, utilization, and expenditures of American Indians and Alaska Natives that are comparable to data for the rest of the population. In our planning, we have consulted with many different parties here in Washington, a wide variety of private groups such as the Health Insurance Association of America or the American Association of Retired Persons, and with a number of nationally recognized researchers and policy analysts.

Question. How long will this study take, and how much will it cost each year?

Answer. We expect the first household data to be available early in 1988 with the final data files anticipated by 1990.

The survey costs for FY 1986 are $2.5 million and $5.5 million in FY 1987. The total cost over the four year period of the survey and development of public use tapes will be $45.0 million. The NCHSR is working with other programs within the Department to arrange for partial financial support for the survey.

7½% SET-ASIDE FROM EVALUATION FUNDS

Question. P.L. 98-551 gave you authority to assess the impact of medical practice patterns and technology on the cost of medical care. Has the Department transferred the required 7-1/2% of Departmental evaluation funds to fund this research?

Answer. Yes, the Department has transferred the full 7½% of funds available from the 1% evaluation set-aside for FY 1986, which amounted to $4.7 million.

Question. Please describe the type of studies this money will support and tell us how this research can actually reduce medical costs in the future.

Answer. These funds support research, mostly extramural, which evaluates the effect of Prospective Payment System and other changes in financing and insurance programs. We also plan to support new projects in the areas of technology assessment, quality of care, financing, and health care organization in addition to several projects which began in FY 1985.

NCHSR is currently supporting studies which we believe will result in future saving in medical care. Some examples of such research are:

- o Small Area Analysis and Medical Practice Variation - a conference in which leaders in the medical field are informed about the amount of variation in practice patterns and the implications of these variations for the costs and quality of medical care, in order to further the effects of organized medicine to reduce the use of inappropriate and extravagant services.

- o Employer Innovations to Control Health Benefit Costs - a study which will describe the programs established by various medium and large firms nationwide to control health care costs, and to estimate the cost savings and policy implications of these innovations.

- o Prevention of Nonelective Hospital Readmissions - a study to determine whether a follow-up nursing care and social services program after hospital discharge reduces unnecessary clinic and emergency room visits or hospital readmissions, and to examine the program's effects on health status and on the costs of medical care.

- o Cost Containment in Primary Care - a study to develop guidelines for providing primary medical care effectively and

economically, and to evaluate the guidelines in terms of changes in hospitalization rates, costs, and quality of care.

- Changing Practice Patterns with Comprehensive Feedback - a study to determine the extent to which physicians will change their practice patterns when they are notified that their patients have longer hospital stays and higher charges than comparable patients of their colleagues.

VARIATIONS IN MEDICAL CARE

Question. In this same line, I understand that there is a large difference in the rates for certain surgical procedures between different geographical regions. Is this true, and if so, can anything be done to control this practice.

Answer. Recent NCHSR sponsorship of research has shown that individual physician practice style may be a more important variable than length of stay in efforts to control health care costs. For example, the hospitalization rate for hysterectomy, tonsillectomy, and prostatectomy showed variations 20 to 30 times that of such conditions as hip fractures and inguinal hernias in the states of Maine, Iowa, and Maryland. When physicians have been presented with data on relative variations in practice, they have voluntarily modified their behavior in ways that lead to a reduction in medical costs with no decrease in quality of care. NCHSR is taking further action by cosponsoring with the American Medical Association a conference to further educate the practicing physician about small area variations.

Additional study of variations in medical care also is an important step to take. New research could effectively explore such issues as:

- Extent and magnitude to variation in medical practice as it affects the Medicare-eligible
- Means to coordinate and integrate the collection of sound epidemiologic data to explain variations in practice.
- Role of differences in practice organization and management, reimbursement, professional education, technology, consumer information, and medical standards.
- Linkage between specific diagnostic and treatment practices and outcome.

HEALTH CARE DELIVERY

Question. It seems that a great deal of effort is being made to bring competition into health care delivery? Do you have any data to show if the consumer is shopping for price when seeking health care?

Answer. The NCHSR is currently funding a study to determine whether providing consumers with information about physician fees has an effect upon consumer behavior. The investigation will distribute a directory with physician fee information to a sample of state employees and Medicare beneficiaries in Oregon. Analyses

of these individuals and control groups will be conducted to measure differences in health care utilization, kinds of services used, physician/consumer interaction, and cost-influenced decisions about physician care.

Question. I understand that Dr. Mason, the former Acting Assistant Secretary for Health, decided that the NCHSR, National Center for Health Statistics and HCFA would all participate in the study and part of its FY 1987 cost would be borne by the the National Center for Health Statistics. Yet, I do not see any indication of this in the NCHS budget request. How will this study be funded, and if NCHS does not participate, will NCHSR have to absorb its cost?

Answer. This study will be funded primarily from NCHSR and HCFA with participation by other elements of the Department and units of the Government which are interested and for whom the findings will be useful. NCHSR will fund the costs which were originally scheduled to be funded by NCHS.

Question. If so, what other programs would have to be reduced at NCHSR?

Answer. The impact on other programs will be determined by the difference between what is available from other sources and that must come from NCHSR.

HEALTH CARE TECHNOLOGY

Question. What is NCHSR doing to improve our understanding of the cost effectiveness of Health Care Technology?

Answer. As examples of the type of research being conducted in health care technology, NCHSR is supporting a proposed study would test the effectiveness of a new type of telephone Cardiopulmonary Resuscitation (CPR) instruction. Previous NCHSR research has demonstrated the effectiveness in saving lives by providing CPR instruction over the telephone. Another study proposes to demonstrate that a computerized infectious disease monitoring system can be used to minimize the inappropriate use of antibiotics, and perform surveillance of hospital-acquired infections more effectively than traditional surveillance systems. The goal of a third proposed study is to reduce the inappropriate use of blood products, a problem with substantial cost implications.

The following is a list of technology assessment projects the Center will address in FY 1986.

-- Economic Information in the Clinical Literature
-- Assessment of Multiple Health Technologies
-- Small Area Variation in Third Molar Extraction Rates
-- Clinical Computer Programs for Ambulatory Care
-- Technology Use and Length of Stay ina 28-NICU Sample
-- Evaluation of Care in the Surgical Intensive Care Unit Environment
-- Identity Change in Cardiac Rehabilitation
-- Quantitative Methods for Technology Assessment
-- Outcomes of PTCA Technology: A Longitudinal Study

-- The Risk of Ceasarean Birth: Patient and Provider Effects
-- APACHE-Based DRG Severity of Illness Modification
-- The Diffusion of Magnetic Resonance Imaging Technology
-- Coping with Stress of Being Denied Heart Transplantation
-- Assessment of Coronary Care Unit Use in Different Hospitals
-- Computer Support for Clinical Research in the Community
-- Treatment Decision Making of Breast Cancer Patients
-- Microcomputer-Based Decision Support for Test Selection
-- Perioperative Geriatric SICU Patient Survey
-- The Cost and Effectiveness of Inpatient Trauma Care
-- Evaluation of Diagnostic Procedures for Cancer Patients
-- The Social Impact of Intensive Care Technologies

CATASTROPHIC ILLNESS COVERAGE

Question. The President has instructed Secretary Bowen to study catastrophic illness coverage. What information does the NCHSR have on this issue, and will it be made available to the Secretary?

Answer. The following is available to the Secretary:

NCHSR has recently supported an analysis of national and Maryland data on catastrophic health care expenditures (Berki, University of Michigan, No. 233- 81-3032). New findings indicate:

o The 5 percent of hospital patients who have catastrophic high cost illness (ranging from $7,500 to $276,632) account for nearly a third of total hospital costs.

o Two-thirds of high cost cases occur in teaching hospitals; two-thirds of these cases involve patients 55 years or older.

o Over one-fourth of those who die while hospitalized are high-cost cases.

o High-cost hospitalizations involve coronary artery bypass surgery, cancer surgery, strokes, and nervous disorders (average hospital bill of $15,000). Average hospital charges were $34,000 for craniotomies, kidney transplants, and extreme immaturity of newborns.

o Medicare paid for nearly 50% of all high-cost discharges in 1981; in 5% of all high-cost cases, and for 17% of high-cost newborns, patients and their families had to pay for the care out-of-pocket.

o Families with high out-of-pocket expenditures for health care relative to their income are disproportionately headed by the young (under 18) or old (over 65), unemployed, with lower income, and with a large uninsured hospital bill.

o About 32% of low income families incurred out-of-pocket expenses exceeding 5% of their income compared to only 5% of high income families.

NCHSR will continue to be involved in such studies.

OCCUPATIONAL HEALTH

Question. This Subcommittee also has responsibility for the funding of another of the Federal statistical agencies, the Bureau of Labor Statistics, and we are aware of a growing interest in data on issues relating to occupational health. Does NCHS plan any new activities in this area?

Answer. No special funding is included in the NCHS budget request for this area. However, NCHS has been increasing its reimbursable activities in this area in recent years, and has had several productive meetings with counterparts at the Bureau of Labor Statistics over the last several months. One of the initiatives is coding occupational and industry information routinely reported to NCHS on the death certificate for each State. Death certificate information provides the national data base for mortality data in such areas as causes of death, life expectancy and infant mortality. In this project, carried out jointly with the National Cancer Institute and the National Institute for Occupational Safety and Health, a total of 30 States and the District of Columbia have been trained in uniform coding procedures for occupation and industry. Of these, 17 are providing data to NCHS, and a total of seven States are being partially reimbursed (the rest are coding the data at no cost to the Federal Government). By linking occupation and cause-of-death information from the death certificate, NCHS can produce valuable information at the State and substate level for occupational mortality surveillance.

At the same time, vital records "follow-back" surveys, which obtain additional information beyond that on the birth or death record from other sources (such as the mother or next of kin), are asking specific questions relative to occupation and its impact on health. Another area NCHS is exploring is the possibility of adding a series of questions to the 1988 National Health Interview survey that will address occupational health issues. Finally, NCHS has recently added a new researcher to the staff with specific responsibility for reviewing all of the Center's data systems to see where data on occupational health can be improved.

NATIONAL AMBULATORY MEDICAL CARE SURVEY

Question. One of the surveys you mention is the National Ambulatory Medical Care Survey, which I understand provides data not only for monitoring of health care use, but is also used in the development of curricula for medical schools. The next scheduled survey should take place in 1988, but it's not clear from your budget request whether or not this will occur. What are your plans for this survey?

Answer. The funding for the National Ambulatory Medical Care Survey (NAMCS) in the budget request is primarily to support analysis of data from previous surveys, and no funding is included for a 1988 survey. As a result, the NAMCS will be postponed until at least 1989.

NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY

Question. The FY 1987 budget includes $3 million for preparation for the next cycle of the National Health and Nutrition

Examination Survey. How long will it take to complete this Survey and what will it cost overall? Does the Administration intend to commit this level of resources to this Survey over the next few years to insure that it is successfully completed?

Answer. In the next National Health and Nutrition Examination Survey (NHANES) program, about 30,000 persons from communities across the U.S. will be examined over a six-year period. National estimates of health and nutritional status for the total and white populations will be available after three years (1991); with considerable oversampling for black and Hispanic persons over the entire six-year period, detailed estimates for these groups would be available when the second three-year cycle would be completed in 1994. Findings of public health or public policy importance recognized at any time during the Survey will be summarized and reported immediately. Overall, the Survey will cost about $74 million over the period 1988-1994. The Administration has demonstrated the priority given to the project by requesting the $3 million in FY 1987.

CUTBACKS IN NCHS NATIONAL SURVEYS

Question. What cutbacks, if any, have been made in the frequency and scope of NCHS national surveys over the last 2 years because of funding reductions? What is the current schedule for conducting these delayed surveys?

Answer. The following surveys have been postponed:

Survey	Original 1981 Schedule	Revised Schedule
National Health and Nutrition Examination Survey	1987	1988
National Survey of Family Growth	1986	1987
National Ambulatory Medical Care Survey	1988	1989

The sample size of the National Health Interview Survey was reduced to 75 percent of its planned level in 1985, and will be reduced to 50 percent of its planned level in 1986. The National Nursing Home Survey was conducted in 1985 at two-thirds of its planned sample size.

NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY

Question. Your FY 1987 request contains an increase that will pay for the National Health and Nutrition Examination Survey. What is the extent of this survey, and what data are you looking for?

Answer. Unlike other surveys, the National Health and Nutrition Examination Survey (NHANES) combines traditional interview methods with intensive physical examinations done in our Mobile Examination Centers. These exams include an extensive physical examination, clinical tests and measurements (such as EKG's, diagnostic ultrasound, chest x-rays, and blood testing). This combination allows us to produce information not available on a national level from any other source (such as the extent of undiagnosed hypertension, diabetes, and gallstones); and to explore relationships between

health and nutrition variables. The ability to explore these associations makes the NHANES study a valuable epidemiologic tool, generating new hypotheses for future clinical research.

Question. How long will this Survey take, and what will be the total cost?

Answer. For the NHANES III, 30,000 persons aged 3 months through 85 years of age will be randomly selected from areas throughout the United States. The Survey will be conducted from 1988-1994 using the NCHS large Mobile Examination Centers. The total cost of the Survey is estimated to be $74 million assuming a modest inflation level over the period of the study.

Question. When will the results be available?

Answer. Results for the total population and whites will begin to be available in 1991 after the initial period of data collection is completed. With continuous oversampling of blacks and Hispanics, results for these groups will begin to be available in 1994. Since the NHANES surveys include the gathering of such extensive information, they result in substantial analyses many years after completion. For example, data from the NHANES studies done in the 1960's and 1970's are still being used to evaluate progress in the battle against heart disease.

Question. How will this data be used and by whom?

Answer. As in the past, data from the NHANES III will be used by Federal and State Government agencies, researchers in universities, medical schools and private industry. Government agencies will use the data to formulate or change programs and policies, to increase basic knowledge through research, and to target intervention programs designed to improve the health of Americans. For example, the Food and Drug Administration will use the data on nutritional status to evaluate the need for changes in food fortification policy. Data on blood pressure, serum cholesterol, smoking, obesity and other risk factors for chronic diseases will be used to evaluate progress on the 1990 Health Objectives for the Nation. The Centers for Disease Control will estimate what proportion of the population has been exposed to the AIDS virus. The National Heart, Lung and Blood Institute will be able to monitor trends in serum cholesterol concurrent with their National Cholesterol Education Program.

INFANT MORTALITY

Question. I have been hearing conflicting data concerning the rates of infant mortality in this country. Please update the Committee on this problem.

Answer. The national infant mortality rate continues to decline although there has been a slowdown in the rate of decline. The latest provisional data for the twelve months ending November 1985 show a national rate of 10.5 deaths per 1,000 live births -- 1 percent below the comparable rate for the previous twelve months.

Neonatal mortality rates have been declining more rapidly than postneonatal rates for the past 20 years. One reason for this is the

major advances that have been made in neonatal intensive care units which treat low birthweight infants.

Question. What kind of differences are we seeing within population centers and among racial and ethnic groups?

Answer. The gap between blacks and whites continues to be a major concern. The latest final data available is for 1983 when the infant mortality rate for blacks was almost twice that of whites:

Infant Mortality by Race
(Deaths per 1,000 live births)

Year	Total	White	Black	Ratio of Black To White
1960.....	26.0	22.9	44.3	1.93
1970.....	20.0	17.8	32.6	1.83
1975.....	16.1	14.2	26.2	1.84
1978.....	13.8	12.0	23.1	1.92
1979.....	13.1	11.4	21.8	1.91
1980.....	12.6	11.0	21.4	1.94
1981.....	11.9	10.5	20.0	1.90
1982.....	11.5	10.1	19.6	1.94
1983.....	11.2	9.7	19.2	1.98

(Note: Provisional data are not available by race)

Birthweight is a major determinant of infant mortality. Blacks are more than twice as likely as whites to deliver a low birthweight infant (white rate is 5.7% vs. black rate of 12.6%). Even when several factors such as age, marital status, month prenatal care began and educational level are controlled simultaneously, black women continue to be twice as likely to have low birthweight babies.

Substantial variations in infant mortality rates exist among the States for both races.

- For the period 1981 - 1983, the rate ranges were:

  --Blacks 16.0 to 24.2 deaths per 1000 live births

  --Whites 8.5 to 11.6 deaths per 1000 live births

- The infant mortality rates for whites were lowest in the states across the North and highest in Appalachian and midwestern industrial areas and some Southern States.

- The infant mortality rates for blacks showed that:

  --Black rates are high in all 27 States with black populations of 150,000 or more.
  --California has the lowest black infant mortality rate (16.0)
  --States with the highest are Illinois (24.0) and Michigan (24.2), reflecting the high rates of Chicago and Detroit.

--Washington, D.C. has one of the highest black infant mortality rates among the States (24.0) and among other large cities.

REIMBURSABLE AGREEMENTS

Question. You have told us that some of your survey costs are funded in part through reimbursable agreements with other agencies. Please identify the agencies involved, surveys involved, and how much each agency is contributing for each survey.

Answer. Listed below by survey or program activity are the anticipated agencies participating in each survey and the estimated amount of contribution:

Major Survey/Program Activity	FY 1987 Estimate
National Vital Statistics	
Health Services and Resources Administration	$50,000
Indian Health Service	30,000
National Institute of Occupational Safety & Health	100,000
National Mortality Followback Survey	
National Institute on Aging	20,000
National Cancer Institute	200,000
National Heart, Lung and Blood Institute	200,000
Veterans Administration	20,000
National Death Index	
National Institutes of Health	200,000
National Heart, Lung and Blood Institute	125,000
National Cancer Institute	10,000
Centers for Disease Control	15,000
National Institute of Occupational Safety & Health	8,000
National Health Interview Survey	
National Cancer Institute	1,025,000
National Survey of Family Growth	
Office of Population Affairs, OASH	625,000
National Institute of Child Health & Human Development	500,000
National Health and Nutrition Examination Survey	
Food and Drug Administration	*/
National Cancer Institute	
National Heart, Lung, and Blood Institute	
Longitudinal Study on Aging	
National Institute on Aging	150,000
Epidemiological Followup Study - NHANES I	
National Institute on Aging	306,000
National Institute on Alcohol Abuse and Alcoholism	51,000
National Institute of Arthritis, Diabetes, Digestive, and Kidney Diseases	105,000
National Institute of Allergy and Infectious Diseases	10,000
National Institute of Mental Health	41,000
National Cancer Institute	102,000
National Institute of Child Health & Human Development	255,000
TOTAL ESTIMATED REIMBURSABLE SUPPORT	$4,148,000

*/Planning is just underway and estimates of amounts of contribution are not yet known.

NCHS REPORT REQUESTED BY THE SENATE

Question. This Committee requested a report concerning the quality and timeliness of data being collected and analyzed by the National Center for Health Statistics.

In this time of budget restraint and rapid rise of health care costs far-reaching policy decisions will be made based on the data supplied by your operation. It should be obvious that these data must be reliable.

Staff informs me that the report is delayed somewhere in the approval process.

- o I want a copy of the report approved by the people at the National Center -- not by OMB.

- o Please have your draft of the report on my desk by close of business today!

Answer. A copy of the requested report as developed by NCHS is being forwarded to the Committee.

NATIONAL VITAL STATISTICS SYSTEM

Question. Some of the most basic information on health is provided by the National Center for Health Statistics (NCHS) through its vital statistics system--such key indicators as infant mortality, life expectancy, and causes of death. Yet, if we listen to the States that provide this data to the National Center for Health Statistics, the system is chronically underfunded and there is a real possibility that the continued viability of this system is in jeopardy. What is the status of this system?

Answer. National vital statistics are produced by NCHS through a system based on cooperative arrangements between the States and the Federal government. The Federal government, through NCHS, funds a share of the costs incurred by the States in producing vital statistics for national use. To date, contractual agreements are in place in all States for two components of the system - birth and death records. In other components, including marriage, divorce, and abortion, we have not been able to fund all eligible States; we obtain a sample of the marriage and divorce data through alternative means such as Census Bureau extrapolation from State microfilm data.

The vital statistics system today is producing high quality data, and we have made considerable progress in NCHS in making this data available to the public in a more timely manner; there are no technical issues that cloud the future of the system.

The primary concern that has been expressed to NCHS by representatives of the States relates to the level of funding for the Federal share of the costs of the system. This share has declined from over 40 percent in the late 1970's to the current level of about 26.5 percent, due to the fact that costs have risen while the level of Federal resources has remained constant or declined. The appropriate level for the Federal share is a matter of some debate - various advisory committees have made

recommendations ranging from 1/3 to 1/2 of the total costs, while the States have argued for a 1/2 Federal share.

NCHS is doing everything possible to assure the continued viability of this important source of data.

LINKED BIRTH AND DEATH

Question. The budget request for the National Center for Health Statistics includes funding for a program to obtain linked birth and death records for more intensive analysis of infant mortality data. Are the States willing to participate in this system despite funding problems with the overall vital statistics system?

Answer. NCHS has been working closely with the State vital statistics offices (and their representative, the Association for Vital Records and Health Statistics), and we are proceeding with a pilot study on linking birth and death records in conjunction with 9 States. Our 1987 budget request includes a total of $0.4 million to expand these efforts. Improving our understanding of infant mortality and its determinants is of extremely high priority to both NCHS and the States.

NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY

Question. As noted in Dr. Macdonald's statement, an increase in funding is requested to support the next National Health and Nutrition Examination Survey. I know how important this is to the medical research community, to nutrition policy, and to other programs under the jurisdiction of this Subcommittee, so I am pleased to see the Administration's support for this survey. Is the amount requested enough for you to proceed with the type of survey that has been planned, or will you have to make compromises?

Answer. That is a difficult question to answer, since we all have the responsibility of balancing our research interests with the reality of living within a budget. NCHS has been very concerned about improving our ability to examine the health problems of various subgroups of the population - particularly Blacks and Hispanics, where former Secretary Heckler's task force on minority health identified significant problems - but also other groups, such as the elderly and low income populations. In our initial planning for the 1988 National Health and Nutrition Examination Survey (NHANES) survey, we had anticipated using a sample size large enough to produce more detailed estimates on these groups in a shorter time period than has been possible in the past. It now appears that our initial planning was overly optimistic in light of fiscal restraints, and therefore, the sample size will not be as large as we had once thought. Despite this change, the NHANES survey will still be providing important information on these population groups, and we are very enthusiastic about the unique information that we will be getting from this survey.

Question. Could you give us a few examples of the types of information that are generated by the National Health and Nutrition Examination Survey?

Answer. Unlike other surveys, the National Health and Nutrition Examination Survey (NHANES) combines traditional interview

methods with an intensive physical examination done in one of our mobile examination centers. These exams include a complete physical, clinical tests and measurements (such as EKG's diagnostic ultrasound, and chest x-rays, and blood testing). This combination allows us to produce information not available on a national level from any other source (such as the extent of undiagnosed hypertension, diabetes, and gallstones); and to explore relationships between health and nutrition variables. The ability to explore these associations makes the NHANES study a valuable epidemiologic tool, generating new hypotheses for future clinical research.

The Environmental Protection Agency has recently decided to speed up the removal of lead in gasoline. This decision was based in part upon information collected in the NHANES II that showed a substantial relationship between the production and use of leaded gasoline and body burdens of lead. Since body burdens of lead have been shown to be related to neurological problems in children, kidney problems and hypertension, this action should result in the prevention of substantial numbers of persons afflicted by these problems.

The leading cause of death in the United States is coronary heart disease and blood cholesterol is an important risk factor for heart disease. The NHANES surveys have been collecting information since 1960 on blood cholesterol levels and plans to continue collecting this information in the future. With this information collected over the decades, we can monitor changes in this major risk factor and plot our progress in reducing the number of people with heart disease. This information will be essential to evaluate the efficacy of the NHLBI National Cholesterol Education Program.

Growth curves from the NHANES surveys are found in every pediatrician's office across the United States and are used to evaluate the health and growth of children. Estimates of dental disease, skin disease and eye disease and need for treatment have been published. In the nutrition area, estimates of iron deficiency anemia, vitamin A deficiency and the relationship between calcium consumption and hypertension have been published. The results from previous NHANES surveys have been published in hundreds of reports and journal articles and serve as a cornerstone of public health knowledge in the United States.

We will be including a number of new areas in the upcoming NHANES. For example, we are working with NCI and CDC on plans to test for the HTLV III virus, the first time such a test will be done on a large-scale, nationally representative sample - and a good opportunity to study the degree to which asymptomatic infection is present in the general population. Incidently, we are also working with CDC and NCI to see if we can test blood samples we have stored from our previous HANES studies.

A second example relates to osteoporosis, a problem that will only increase as the population grows older. Our measures will include bone mineralization and calcium intake, important to current research in this area.

COLLABORATION WITH OTHER AGENCIES

Question. Your budget request, as well as other documents we have seen on the National Center for Health Statistics, refers to work done in collaboration with other agencies of the Public Health Service. Will the cuts proposed by the Administration in funding for NIH and other agencies cause further reductions in programs of the National Center for Health Statistics?

Answer. We work very closely with each of the agencies of the PHS in the design, conduct, and analysis of many NCHS surveys. Some examples of these collaborative projects include:

- the National Mortality Followback Survey, where we are looking at risk factors for heart disease in collaboration with National Health Lung and Blood Institute, and looking at other aspects of premature death and the care received in the last year of life, in conjunction with a number of other agencies;

- the longitudinal followup of persons included in the 1971-85 National Health and Nutrition Examination Survey where we are working with several of the NIH Institutes and other agencies to examine how health characteristics and risk factors observed over 10 years ago relate to present health conditions; and

- with National Cancer Institute, we plan to conduct a major supplement to the 1987 National Health Interview Survey to examine cancer risk factors.

NCHS relies a great deal on both the scientific expertise and funding support of the Institutes and, in return, NCHS provides data of considerable importance to the research conducted by NIH. Certainly, the funding available to these agencies determines their ability to support NCHS programs, but at this point in the budget process it is unclear to what extent proposed funding levels for NIH or other PHS agencies will impact on NCHS programs.

SURVEYS OF HEALTH CARE UTILIZATION

Question. In the last several years, we've seen a tremendous amount of change in the way medical care is being delivered--new group practice arrangements for physicians, more surgery and other medical procedures being done outside of hospitals, etc. Does the National Center for Health Statistics have adequate data systems in place to tell us what these changes mean to the types of health care Americans are getting, and what the implications are for national health policy?

Answer. NCHS has four major surveys of health care providers - the National Hospital Discharge Survey, the National Ambulatory Medical Care Survey, the National Nursing Home Survey, and the National Master Facility Inventory. These surveys provide important data on the three largest components of the health care system - acute care hospitals, physicians practicing in private offices, and nursing homes. Household surveys, such as the National Health Interview Survey and the National Survey of Family Growth, provide additional information on health care utilization of individuals, but without the detail available from studying the records of providers.

Although these surveys continue to provide important information, their coverage is limited to traditional sites of medical care. As the organization and financing of health care has rapidly changed in recent years, and cost containment has become a predominant concern, rapid growth has occured in alternative modes of delivery - physician group practices, community-based home health care services, "surgi-centers" and walk-in clinics, etc. Our existing surveys are limited in their ability to assess care in these alternative sites.

Question. I think this is a very important area, and I would appreciate it if you could provide us with more information on these proposals, including estimated resource requirements, for the record.

Answer. In the past, NCHS has proposed expanding the National Ambulatory Medical Care Survey to include physicians practicing in hospital outpatient clincs and emergency rooms; however, resources have not been available.

NCHS is currently looking at ways to restructure its existing surveys of health care providers to address these areas, and to allow for follow-on studies of patients to measure the outcomes of health care. Such an approach would allow the measurement of shifting patterns of health care delivery, as well as to assess the impact on quality and health outcomes from different sources of care, medical procedures, and other differences in medical care. NCHS is still at a very preliminary stage with these plans, and is preparing a planning paper for review within the Public Health Service. It is not yet possible to determine resource requirements, although to some extent it is expected that funding from existing surveys of health care providers would be used to support the restructured approach.

IMPACT OF SEQUESTRATION ON AFL PROJECTS

Question. What is the anticipated impact on projects funded in FY 1986 resulting from the sequestration of funds under P.L. 99-177? Will projects be reduced equally?

Answer. The Adolescent Family Life (AFL) program reductions resulting from the sequestration will be taken equally from the funds set aside for continuation and new grant funding. We anticipate that the sequestration of funds in FY 1986 will not severely affect the level of services that can be provided.

Most of the AFL's current grantees are now operating on FY 1985 funds since last years grant awards were made in September 1985. The sequestration reductions will not affect these grantees until their projects come up for continuation funding in September 1986. Program staff will work with them to help minimize reductions in services wherever possible.

Funds set-aside to support new demonstration and research grants in FY 1986 will also be reduced by 4.3 percent. Program staff will encourage new demonstration grantees to look for higher levels of community support toward the total cost of their projects. The recent media attention to adolescent pregnancy should be helpful in

that regard. Research proposals for smaller, less expensive studies will also be encouraged.

AFL DEMONSTRATION GRANTS

Question. Please provide us with a list of Adolescent Family Life grantees for FY 1986, indicating the year in the grant cycle of each (i.e., which are in the first year, second year, and so on through the fifth year)? Will those in the fifth year be terminated at the end of FY 1986?

Answer. The following listing includes the names, locations, and project periods for the 79 demonstration grants funded at the end of FY 1985 (the last funding cycle completed). The initial AFL grants were funded in FY 1982 and are now in their fourth funding cycle. Of this group, those that were awarded five-year grants will complete their fifth year with FY 1986 funds. AFL legislation does not permit funding of any project for a period in excess of five years. Community level support for projects must be demonstrated prior to initial grant awards to ensure that they will be continued after the AFL project period is completed. Therefore, even though program funding by HHS ceases at the end of the project period, it is likely that the projects previously supported by AFL will not be terminated.

ADOLESCENT FAMILY LIFE DEMONSTRATION GRANTS

Type	Grantee	City	State	Project Start	Period End
First Year Grantees					
P	American Red Cross	Washington	DC	10/85	09/88
C	Nat'l Conference of Cath Char	Washington	DC	10/85	09/88
C	Community Health Clinics, Inc	Nampa	ID	10/85	09/88
P	Committee on Status of Women	Glenview	IL	10/85	09/88
C	University of IL, School of Social Work	Urbana	IL	10/85	09/88
P	Lutheran Fam Ser of NW IN	Merrillville	IN	10/85	09/88
C	Our Lady of Providence Ch Ctr	W Springfield	MA	10/85	09/88
P	Boys Clubs of America	New York	NY	10/85	09/88
C	RI Dept of Human Ser	Cranston	RI	10/85	09/88
C	Florence Crittenton Home & Hosp	Charleston	SC	10/85	09/88
P	SD Dept of Health	Pierre	SD	10/85	09/88
C	Utah State University	Logan	UT	10/85	09/88
P	American Assn for Couns & Dev	Alexandria	VA	10/85	09/88
Second Year Grantees					
C	Sisters of Charity Hh Sys Inc	Lewiston	ME	10/84	09/89
P	Medical Care Development, Inc	Augusta	ME	10/84	09/87
C	Exchange Club Parent/Child Ctr	Jackson	MS	10/84	09/89
C	Young Families Program, Inc	Billings	MT	10/84	09/89
P	Montana State University	Bozeman	MT	10/84	09/86
P	Southern Tier Off of Social Ministry	Elmira	NY	10/84	09/89
C	Covenant House	New York	NY	10/84	09/89
C	Bank Street College of Education	New York	NY	10/84	09/87
P	National Urban League	New York	NY	10/84	09/87
C	Salvation Army Maternity Home	Tulsa	OK	10/84	09/89
P	Margaret Hudson Program, Inc	Tulsa	OK	10/84	09/89
C	Caguas Regional Hospital	Caguas	PR	10/84	09/89
C	Univ of TX Health Sciences Cen.	Dallas	TX	10/84	09/89
C	Adoption Services of WACAP	Port Angeles	WA	10/84	09/89

Third Year Grantees

P	COSSMHO	Washington	DC	10/83	09/86
P	Emory University	Atlanta	GA	10/83	09/87
C	Parent & Child Development Cen.	Savannah	GA	10/83	09/88
C	Dept of Public Health & Soc Serv	Agana	GU	10/83	09/88
P	Family of the Americas Fdn	Mandeville	LA	10/85	09/86
P	Search Institute	Minneapo'is	MN	10/83	09/88
C	Father Flanagan's Boy's Home	Omaha	NB	10/83	09/86
C	La Clinica de Familia, Inc	Las Cruces	NM	10/83	09/88
C	Manpower Demonstration Research Corp	New York	NY	10/83	09/86
C	Young Women's Christian Assn	Salem	OR	10/83	09/88

Fourth Year Grantees

C&P	Charles Henderson Child Health Center	Troy	AL	10/82	09/87
C&P	Tucson Unified Sch District #1	Tucson	AZ	10/82	09/87
C	Family Services Agency of San Francisco	San Francisco	CA	10/82	09/87
C&P	Child Opportunity Program, Inc	Denver	CO	10/82	09/87
C&P	Eastern Conn Parent-Child Center	Putnam	CT	10/82	09/86
C&P	Hill Health Corp	New Haven	CT	10/82	09/87
P	Gallaudet College	Washington	DC	10/82	09/86
C	Economic Opportunity	Miami	FL	10/82	09/87
C	Young Women's Christian Assn	St Petersburg	FL	10/82	09/87
C	Cities-in-Schools, Inc	Atlanta	GA	10/82	09/87
C	State of Hawaii, Dept of Health	Honolulu	HI	10/82	09/87
C	Hull House Assn	Chicago	IL	10/82	09/87
C	City of Gary	Gary	IN	10/82	09/87
C&P	Lyon County Health Dept	Emporia	KS	10/82	09/87
C	Lexington-Fayette County Health Department	Lexignton	KY	10/82	09/87
P	Dept of Hlth and Human Resources	New Orleans	LA	10/82	09/87
C	Women's Advocacy Bureau	Baton Rouge	LA	10/82	09/87
C	St. Ann's Infant & Matern Home	Hyattsville	MD	10/82	09/87
C&P	St. Margaret's Hospital	Dorchester	MA	10/82	09/87
P	Catholic Social Service of Wayne Co	Detroit	MI	10/82	09/87
C	Wayne County Intermediate School District	Lincoln Park	MI	10/82	09/87
P	Minnesota Institute	Anoka	MN	10/82	09/86
C	St. Paul-Ramsey Medical Center	St. Paul	MN	10/82	09/87
P	SEMO Assn of Public Health Adm	Kennett	MO	10/82	09/87
C	Visiting Nurse Assn	Manchester	NH	10/82	09/87
C&P	Camden County Dept of Health	Camden	NJ	10/82	09/87
P	Mt Vernon Public Schools	Mt Vernon	NY	10/82	09/87
C&P	Greene County Health Care	Snow Hill	NC	10/82	09/87
C	The Guidance Center	Smethport	PA	10/82	09/87
C	Maternal & Family Health Svcs	Wilkes Barre	PA	10/82	09/87
C	Providence Ambulatory Health Care Fdn	Providence	RI	10/82	09/87
C&P	St. Mary Human Development Ctr	Ridgeland	SC	10/82	09/87
P	University of South Carolina	Columbia	SC	10/82	09/87
C&P	Douglas Cherokee Economic Authority	Morristown	TN	10/82	09/87
C&P	Catholic Family Service	Amarillo	TX	10/82	09/87
C	University of Utah	Salt Lake Cy	UT	10/82	09/87
P	Brigham Young University	Provo	UT	10/82	09/87
C&P	Addison County Parent/Child Cen	Middlebury	VT	10/82	09/87
C	Norfolk State University	Norfolk	VA	10/82	09/87
C	Tacoma-Pierce County Health Dept	Tacoma	WA	10/82	09/87
C&P	Memorial General Hospital Assn	Elkins	WV	10/82	09/87
C	Family Hospital	Milwaukee	WI	10/82	09/87

Type of Grant

"C" means Care
"P" means Prevention
"C&P" means Combination

CARE AND PREVENTION PROJECTS

Question. Please provide statistics showing the breakdown between care services and prevention services provided by the Adolescent Family Life projects.

Answer. The Adolescent Family Life Act requires that at least two-thirds of program funds must support demonstration projects for services and not more than one-third of the (services) amount can support prevention projects.

The following table illustrates how program funds were allocated in FY 1985 and estimates of FY 1986 and FY 1987 allocations:

Demonstration Grants:	FY 1985	FY 1986	FY 1987
Services (Care) Projects	$6.7M	$6.0M	$8.3M
Prevention Projects	2.9M	2.6M	2.7M
Combination Projects	2.2M	2.0M	---
Total	$11.8M	$10.6M	$11.0M

TEEN PREGNANCY DATA ARCHIVE

Question. What is the status of the teen pregnancy data archive funded under the AFL program in FY 1982?

Answer. The archive project has had as its goal to identify and make available the most valuable data sets in adolescent pregnancy and family planning to expedite the work of researchers, practitioners, and policy-makers in these areas. Around 50 such data sets are now available and being publicized; user-training workshops also are being provided to assist less-experienced data users. Further acquisitions to bring the archive holdings to 80 - 100 data sets are underway. The original FY 1982 contractor was replaced in FY 1984 by Sociometrics Corporation, whose contract runs to September 1986.

RESULTS OF ADOLESCENT FAMILY LIFE GRANTS

Question. Your program has now been in operation since 1982. What kind of results are being reported from your grantees?

Answer. Initial grant awards for demonstration projects were made in September 1982. Most of these awards were for five year project periods and final results will not be available until they are completed. However, preliminary results are continually being reported on continuation applications, end-of-year reports and annual workshops.

Care projects - results are focused on outcomes generated from mandated services which usually fall in four categories: health, education, financial, and social outcomes. Although the results are preliminary, some sites have been reporting successes in the following areas:

-- improvements in health outcomes - reduction in the incidence of low birth weight babies, reduction of pre-term babies, and

reduction in the number of complications for both mother and baby for their clients as compared to non-program clients.

-- improvements in educational and job related outcomes - produced a higher proportion of clients that completed high school or its equivalent than is found among non-client teen parents. Those program focusing specifically on job related goals report successes in helping clients acquire the credentials and skills necessary to support themselves.

Prevention projects - results are focused on postponement of sexual activity and factors which are assumed to be associated with postponement. Although results from prevention activities are by their very nature longer-term than those from care projects, findings that have been reported include:

-- an increase in communication about sexual issues between parents and teens;

-- an increase in the comfort level in discussions of sexual issues between parents and teens;

-- an increase among parents in confidence at being able to respond appropriately to sexuality issues; and,

-- an increase among parents accepting their responsibility for the sexual education of their children.

Whether or not these improvements in teen-parent communication will have an impact on local teenage pregnancy rates is yet to be proven. Several of the program evaluations will present findings on this question in their final evaluations.

Question. Can you demonstrate a significantly lower rate of teenage pregnancy in areas where you have been supporting programs?

Answer. Pregnancy rates are difficult to measure, and are generally only estimates on a statewide or larger basis. We cannot demonstrate decreases in rates of adolescent pregnancy in a large area as a result of a localized prevention project. Effects of prevention projects are difficult to measure, and positive results may occur only several years after the intervention, particularly when the focus of the project is on very young teens or pre-teens.

We have, however, demonstrated a measurable effect of repeat pregnancies. Teens who have had a prior pregnancy are at a much higher risk of becoming pregnant again than other teens. Eleven AFL care projects have reported repeat pregnancy rates that average 10.5% for clients within a year of delivery. That is considerably below the 15% rate reported by the Allen Guttmacher Institute that occurs on a national level for teens in the same age group.

ADOPTION

Question. Adoption has been promoted as a viable choice for the pregnant teenager to make. How many adolescent mothers are choosing this option?

Answer. Last year, 239 adolescent mothers receiving care services at AFL projects choose the adoption option for their babies.

Question. Have you supported any follow-up studies that would study the long-term effects that adoption may have on the teenage mother?

Answer. Yes. In FY 1984, the Battelle Institute of Seattle was awarded a two-year research grant to study differential outcomes for teen mothers who choose an adoption plan and adolescents who decide to raise their infants. Outcomes being compared include educational attainment, marriage, subsequent fertility, earned income, and public-sector support. Results of the study should be available within the next year.

ADOLESCENT FAMILY LIFE GRANT PROGRAM

Question. Funding for the Adolescent Family Life (AFL) program was just under $15 million each of the Fiscal Years 1985 and 1986 (prior to sequestration); the budget request for FY 1987 is also just under $15 million. Your budget proposal for FY 1987 indicates that you expect to increase the number of grantees to 97 in FY 1987 (up from 90 in FY 1986 and 88 in FY 1985). How do you anticipate doing this with no funding increases?

Answer. In FY 1987, a total of 97 grantees are expected to be funded, the same level as is currently estimated for FY 1986. In FY 1986, 43 demonstration grants will complete their project periods. Included in these completions will be 39 projects initially funded in FY 1982 for 5 years and 4 projects supported for shorter project periods. Funding for the 36 new demonstrations will come from the turnover of funds previously allocated to these projects. In the research program, 5 grantees will complete their project periods with FY 1986 funding and we anticipate that 5 new research grants can be supported in FY 1987.

Question. What will be the average grant amount in FY 1987 as compared with previous years?

Answer. Average grant awards for demonstration and research projects for the three years are:

	(dollars in thousands)		
	FY 1985	FY 1986	FY 1987
Demonstration Grants	$150	$132	$137
Research Projects	$100	$81	$84

Question. How will this affect the program supported by these grants?

Answer. We anticipate that with increased program staff support provided to the continuation and new grantees that any negative impact on the services provided will be minimized.

IMPACT OF AFL FINDINGS OF TEEN PREGNANCY RATES

Question. What data exist on the use of findings from Adolescent Family Life demonstration projects and on the impact they have had on teenage pregnancy rates?

Answer. Initial grant awards for demonstration projects were made in September 1982. Most of these awards were for five year project periods and final results will not be available until they are completed. However, findings from the demonstration projects are continually being retrieved and disseminated, i.e.:

-- Many grantees have expressed interest in collecting and maintaining their client data according to common specifications. This "common data set" will provide a valuable source of data on teen pregnancy in the future for researchers and evaluators who wish to compare approaches or examine differential effects across different groups of teens. Data generally fall in four catagories for care sites: demographic characteristics, education and financial information, health information, and follow-up information for mother and baby collected at delivery, 6, 12 and 24 months post-partum.

-- A data archive has been set up through a contract where data on adolescent pregnancy and prevention are deposited and are made readily available to anyone interested in these issues. Eventually we anticipate data from AFL funded research projects and the "common data set" will be available to interested parties.

-- A summary of all projects now in operation is presently being finalized for distribution. Summaries of preliminary findings of each site are included.

-- Public media resources, such as professional journals, public forums and meetings, community newspapers and publication of State and local organizations are already being utilized to report program accomplishments and findings. This will likely increase as projects move into their final years of operations.

-- Some States like California and Washington have already adopted models from AFL funded demonstration sites located in their states and implemented them state-wide.

Question. Have you begun to analyze this data? If so, when can we expect a report?

Answer. AFL legislation requires that each demonstration project have an internal evaluation component designed to test hypotheses specific to that project's service delivery model. Projects are evaluated by an independent evaluator contracted by each grantee. Individual evaluation progress reports are received on continuation applications, end-of-year reports and annual workshops. Final reports from each of the demonstration projects will be available when the projects are completed. Analysis of these final reports will be conducted at that time.

TEENAGE SUICIDE

Question. I know that the Adolescent Family Life program's primary interest is in teenage sexuality and pregnancy. However, the February 24 issue of Time magazine indicates that the rate of suicide in the 15-19 year age group has almost tripled since 1958. Are any of the project grants that are supported by your agency addressing this problem? If so, can you describe for us what is being done? If not, do you have any plans in this area?

Answer. Early teen sexual activity and teen pregnancy appear to be symptomatic of a much broader picture of self-destructive behavior among teens. Factors that affect teen pregnancy, such as problems of family structure and functioning and low teen self-esteem, are also associated with other forms of teen risk taking behaviors such as teen suicide and drug and alcohol abuse.

The Adolescent Family Life Act provides funds specifically for addressing the issue of teen pregnancy, but obviously the problem cannot be dealt with in isolation from other problems. All grantees are required to offer referral for mental health services. They also must maximize the role of the family in helping the teen, and involve religious, charitable and voluntary organization in the provision of services. Many AFL grantees use their funds to support a teen pregnancy component of a larger effort to provide counseling or health care to troubled teens generally.

We do support project grants in the area of teen suicide, principally through the National Institute of Mental Health located in the, Alcohol, Drug Abuse, and Mental Health Administration. These are some of the things currently being done:

A study of childhood depression may provide clues to the relationship between serious affective illness and suicidal behaviors in children ages 6-12. Findings suggest that the severity of depression in children with suicidal ideation is significantly greater than in children without suicidal ideation. Using both clinical and community samples, preliminary analyses show that 9 of 17 symptoms of depression were rated as more severe for those children who reported suicidal thoughts or who had actually attempted suicide.

In addition, a controlled study will provide the first systematic information about the etiology of adolescent suicide, producing findings which could provide the basis for rational treatment and prevention. The aim of the study is to develop a diagnostic profile of suicide completers based on an interview with parents, teachers, and peers, and on documents prepared during the adolescent's lifetime. Using this "psychological autopsy" method, very preliminary data from a sample of 109 suicides show that 63% were between 17-19 and that the majority were white males. The most frequent methods were hanging and shooting. About 30% had made previous suicide attempts. About 50% of the sample had seen a mental health professional before committing suicide.

A two phase activity on the assessment and treatment of child and adolescent depression will begin in June 1986. Experts on diagnosis, pharmacotherapy, and psychosocial therapies will meet to

discuss critical issues and problems in the conduct of research on affective disorders in adolescence. The relationship of suicide to depression will be explored. The product of these research activities will be a strategy for research development in these understudied areas.

In addition to funding the continuation of the psychological autopsy study of completed suicides in adolescents, a new complementary family study of completed adolescent suicides will be supported.

A Workshop on Assessment and Treatment of Childhood Depression will be held in June 1987. Several new applications for research on child and adolescent suicides are anticipated for March and June NAMHC, 1987, based on technical assistance provided to the potential applicants.

SMOKING AND HEALTH ACCOMPLISHMENTS

Question. You are proposing a budget of $3.5 million for the Office of Smoking and Health. I totally agree that smoking is bad for your health. I am concerned, however, what the $3.5 million is actually accomplishing. Please describe some of the real accomplishments of the program.

Answer. The scientific and public information program within the Office on Smoking and Health has been the center for all smoking and health activities since its creation after the first report of the Surgeon General. At that time, over half of adult males and slightly over one-third of adult women were regular smokers. In 1985, smoking among adult males has declined to 35 percent, a level we probably have not seen since around World War I. Smoking among women has declined, although not to as great a degree as observed among men. Per capita consumption reached its zenith in 1963 at 4,345 cigarettes per person, the year before the Surgeon General's report was released. In 1985, per capita consumption was less than 3,400 or a decrease of nearly 1,000 cigarettes annually. Total cigarette consumption has decreased by almost 40 billion since 1982.

Mortality data confirm the impact of these declines. Coronary heart disease rates for males has been declining since the late 1960s and recent estimates have projected that decreases in smoking among men is responsible for around 25 percent of this decline. Recent reports by the National Cancer Institute indicate that lung cancer death rates among men are also beginning to level off and should begin to show substantial declines soon.

Question. Can you show any data, for example, that your educational activities have actually reduced the number of teenage smokers and pregnant smokers?

Answer. A number of national surveys have observed declines in adolescent smoking rates since the latter part of the 1970s. Not only has the percent of current smokers among teenagers declined but we have proportionately fewer ever smokers among this age group as well, indicating fewer teenagers are initiating the smoking behavior today compared to previous cohorts. For example, smoking

rates among high school seniors declined from 29 percent in 1976 to just 19 percent in 1984. Estimates from national probability surveys of adolescents have also noted declines in regular use of cigarettes. Today smoking by teenage boys may be the lowest rates observed in this country since the 1920s and teenage girls are also showing signs of declining after many years of steady increases. Data from the National Natality Survey indicate that approximately one in five married women stop smoking during their pregnancy. While it is impossible to show what impact individual education programs have on smoking behavior, there can be no doubt that people's awareness of the health consequences and concern over them are directly responsible for the changes observed in smoking rates over the last 20 years.

PHS SMOKING AND HEALTH ACTIVITIES

Question. Other than the $3.5 million requested in your budget, do other agencies in the Public Health Service, the Cancer Institute, for example, have programs such as yours?

Answer. Yes, many agencies carry out programs of education and information, not primarily directed to specific audiences; many are conducted jointly with the Office on Smoking and Health. For example, the Office in conjunction with the Cancer Information Service of the National Cancer Institute (NCI) have sponsored several educational efforts over the past years. Public service announcements prepared by the Office on Smoking and Health for the NCI's Cancer Information Service have generated more viewer telephone response than any other television material ever developed for the Service.

Within the Centers for Disease Control, the Center for Health Promotion and Education carries out a considerable smoking and health effort primarily through their risk reduction activities with state and local health departments.

The National Heart, Lung, and Blood Institute is now beginning a program which will work exclusively with physicians and other health professionals, examining the clinical opportunities available for the office management of smoking. This project was initiated last year and the Office on Smoking and Health was closely involved in its planning and implementation.

Question. What is the total expenditure for smoking and health in the Public Health Service?

Answer. The Public Health Service will be spending approximately $45.2 million in 1987 to combat smoking and understand its destructive effects on health. The majority of these expenditures are within the National Institutes of Health and are primarily in support of direct biomedical research on the health consequences of smoking. Other principal participants are the Office on Smoking and Health, the Alcohol, Drug Abuse and Mental Health Administration, and the Centers for Disease Control.

PHS Smoking and Health Activities
(dollars in $000)

	FY 1985 Actual	FY 1986 Revised	FY 1987 Request
NIH			
Cancer	$21,131	$23,234	$24,713
Heart, Lung & Blood	10,375	10,465	10,141
Environmental Health	519	517	503
Child Health	1,316	1,300	1,300
Research Resources	730	717	652
NIH, Subtotal	(34,071)	(36,233)	(37,309)
ADAMHA			
Drug Abuse	4,364	3,535	3,641
OASH			
Smoking and Health	3,531	3,375	3,471
CDC			
Chronic & Environmental Health	375	755	755
PHS Total	$42,341	$43,948	$45,176

SMOKELESS TOBACCO

Question. What is the status of the Surgeon General's study on the health consequences of smokeless tobacco use?

Answer. A pre-publication copy of The Health Consequences of Using Smokeless Tobacco was released on April 1, 1986. A final copy will be published in June. This comprehensive review of the existing scientific evidence on the health effects of smokeless tobacco was undertaken at the request of the Federal Trade Commission. It was compiled by the Advisory Committee on the Health Consequences of Using Smokeless Tobacco, chaired by Dr. Joseph Cullen of the National Cancer Institute. The Office on Smoking and Health played an advisory role to Dr. Cullen and the Committee by supplying technical assistance and providing access to hundreds of studies available within the Office's Technical Information Center.

Question. Do you have any preliminary data to report?

Answer. This report discusses the health consequences of smokeless tobacco use. It constitutes a comprehensive review by an Advisory Committee to the Surgeon General of the available scientific literature to determine whether using smokeless tobacco increases the risk of cancer and noncancerous oral diseases and effects, leads to addiction and dependence, and contributes to other health consequences.

After a careful examination of the relevant epidemiologic, experimental, and clinical data, the Advisory Committee concluded that the oral use of smokeless tobacco represents a significant health risk. It is not a safe substitute for smoking cigarettes.

It can cause cancer and a number of noncancerous oral conditions and can lead to nicotine addiction and dependence.

The major overall conclusions of this report are the following:

- It is estimated that smokeless tobacco was used by at least 12 million people in the United States in 1985 and that half of these were regular users. The use of smokeless tobacco, particularly moist snuff, is increasing, especially among male adolescents and young male adults.

- The scientific evidence is strong that the use of snuff can cause cancer in humans. The evidence for causality is strongest for cancer of the oral cavity, wherein cancer may occur several times more frequently in snuff dippers compared to nontobacco users. The excess risk of cancer of the cheek and gum may reach nearly fiftyfold among long-term snuff users.

- Some investigations suggest that the use of chewing tobacco may also increase the risk of oral cancer, but the evidence is not as strong and the risks have yet to be quantified.

- Experimental investigations reveal potent carcinogens in smokeless tobacco. These include nitrosamines, polycyclic aromatic hydrocarbons, and radiation-emitting polonium. The tobacco-specific nitrosamines often have been detected at levels 100 or more times higher than Government-regulated levels of other nitrosamines permitted in foods eaten by Americans.

- Smokeless tobacco use can lead to the development of oral leukoplakias (white patches or plaques of the oral mucosa), particularly at the site of tobacco placement. Based on evidence from several studies, a portion of leukoplakias can undergo transformation to dysplasia and further to cancer.

- Gingival recession is a commonly reported outcome of smokeless tobacco use.

- A number of studies have shown that nicotine exposure from smoking cigarettes can cause addiction in humans. In this regard, nicotine is similar to other addictive drugs such as morphine and cocaine. Since nicotine levels in the body resulting from smokeless tobacco use are similar in magnitude to nicotine levels from cigarette smoking, it is concluded that smokeless tobacco use also can be addictive. Besides, recent studies have shown that nicotine administered orally has the potential to produce a physiologic dependence.

- Some evidence suggests that nicotine may play a contributory or supportive role in the pathogenesis of coronary artery and perpheral vascular disease, hypertension, peptic ulcers, and fetal mortality and morbidity.

EFFECTS OF PASSIVE SMOKING

Question. What is the status of the report on the effects of passive smoking and can you provide us with any preliminary data?

Answer. Two major activities addressing the effects of passive smoking are underway. First, an entire review of the epidemiological and related literature will be presented as the 1986 Surgeon General's Report, which is scheduled for release late this year. Second, the Office, in collaboration with the Environmental Protection Agency, last year requested the National Academy of Science to look at the topic. Specifically, we are interested in an assessment of exposure to passive smoking environments and how such exposure is correlated with the health effects as reported published literature. Information resulting from these lines of investigation will be shared as it becomes available.

CIGARETTE ADDITIVES

Question. Public Law 98-474 required cigarette manufacturers to provide the Secretary of Health and Human Services a list of ingredients added to cigarettes (with confidentiality assured). Is this law being observed and enforced?

Answer. Last year the Department published a notice in the Federal Register which specified the format and reporting requirements for such ingredients which must be received from manufacturers, packagers, and importers of cigarettes. The Office on Smoking and Health has put into place a system which protects the confidentiality of such ingredients in compliance with the legislation.

Question. Has the Department received or studied these additives for long-term toxicity? If so, where is this being carried out?

Answer. Each manufacturer, packager, and importer of cigarettes has until April 2, 1986 to report those ingredients added to cigarettes in the format specified in the Federal Register. After receipt of all lists, the Department will be in a position to decide how best to proceed with evaluation of these substances.

STATUS OF 1990 HEALTH OBJECTIVES

Question. What is the status of the Department's effort to achieve the 1990 health objectives?

Answer. During 1985, we undertook a midcourse review of the 15 priority areas and the status of each of the 227 objectives. The results of this review are now being prepared for publication later this year. Based on draft reports of the status of each objective,

we can tabulate the following statistical profile of their progress to date:

Percent of objectives already met	13%
Percent of objectives on track to be met	32%
Percent of objectives unlikely to be met	25%
Percent of objectives lacking data	28%

A midcourse review of the overall goals to reduce mortality in age groups of the population, enunciated in Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention (1979), shows the following progress (based on 1984 provisional data):

Age Group	1978 Base 1/	1984 1/	1990 Goal 1/
0 - 1 year	14.1/1,000	10.6/1,000	9.0/1,000
1 - 14 years	42/100,000	32/100,000	34/100,000
15 - 24 years	115/100,000	99/100,000	98/100,000
25 - 64 years	533/100,000	447/100,000	400/100,000

1/ 0 - 1 year: deaths per 1,000 live births
1 - 64 years: deaths per 100,000 population

Question. What kinds of assistance have you provided to States in their efforts to implement the 1990 health objectives?

Answer. A recently conducted study of State implementation of the 1990 health objectives found that 40 States plus the District of Columbia have implemented some health promotion and disease prevention programmatic efforts reflecting the national 1990 health objectives. Federal assistance to States has included: a cooperative agreement project supported by the Office of Disease Prevention and Health Promotion (ODPHP) with the Public Health Foundation to link State health departments to the information tracking system developed by ODPHP for the 1990 objectives; direct assistance of the ODPHP director and staff at State-level Objectives conferences in the New England region, Tennessee, Hawaii, Montana, Louisiana, West Virginia, and other States; and, extensive technical assistance to State health education officers of State health departments by staff of the Center for Health Education and Promotion (Centers for Disease Control). Information developed by ODPHP in support of the 1990 health objectives is routinely disseminated to State health officers.

HEALTH PROMOTION FY 1986 BUDGET REDUCTION

Question. Your FY 1986 budget was reduced by about $500,000 by this Committee. What specific projects are affected or lost due to this budget reduction?

Answer. As a result of the $539,000 reduction in the FY 1986 appropriation, seven of the office's continuing cooperative agreements with national membership voluntary and professional organizations will not receive funding this fiscal year, but will have their project periods extended to cover 1986 activities. Those seven organizations include:

American Dietetics Association/Society of Nutrition Education
Health Insurance Association of America
American School Health Association
American Association of School Administrators
Boys Clubs of America
National Council on Aging
Public Health Foundation

Only the Workplace Health Fund (AFL-CIO) cooperative agreement was exempted from this reduction pursuant to the FY 1986 Conferees report.

In addition to reducing support for continuing cooperative agreements, plans to award several new agreements in FY 1986 have been cancelled. Another step taken to meet this decrease in funds was to reduce technical assistance to the States in conjunction with the "Healthy Older People" campaign.

HEALTH PROMOTION

Question. The Office of Disease Prevention and Health Promotion in OASH facilitates the collaboration between Federal and non-Federal groups to develop and implement national strategies and programs to prevent disease and disability and promote good health. Health initiatives are supported through cooperative agreements with the private and voluntary sectors. How many cooperative agreements to stimulate health promotion will be supported in FY 1987? What types of health promotion activities will these agreements support and what groups of people will they reach?

Answer. In 1987, the Office of Disease Prevention and Health Promotion (ODPHP) plans to support continuation of eight cooperative agreements. They are:

Workplace Health Fund (AFL-CIO) - a project to develop labor union support and sponsorship for health promotion programs at the worksite intended to benefit union members and other workers.

Health Insurance Association of America - a project to transfer the clinical preventive services system developed for use in Health Maintenance Organizations (under the name Project INSURE) to Preferred Provider Organizations (PPOs), intended to benefit users of that form of health care delivery system by extending proven preventive interventions as a part of their regular health care.

American School Health Association - a project to package the 1990 Health Objectives relevant to school-age children for use in school health education curricula and to gain acceptance and ensure use of these materials by local school districts, intended to benefit the school-age population.

American Association of School Administrators - a project to transfer to additional States an effective school health education program, which was developed in Oregon, based on contracting with local school officials, and intended to benefit the school-age population.

American Dietetics Association/Society for Nutrition Education - a project to develop guides for implementing better nutrition through meals and snacks available at worksites, with special attention to small worksites that do not have cafeterias, intended to benefit workers.

Boys Clubs of America - a project to develop materials to help local Boys Clubs teach latch-key children how to protect themselves more effectively against violence and sexual abuse and to assist local clubs to become effective in using the materials, intended to benefit low-income children.

National Council on Aging - a project to establish a central clearinghouse of materials and programs on health promotion and disease prevention for older Americans, intended to benefit the many local and State agencies that can help to disseminate these materials and sponsors such programs and thus to benefit older persons.

Public Health Foundation - a project to make the ODPHP Information Tracking System for the 1990 health objectives accessible and usable by State health departments and to assist States in using successful implementation approaches developed by other States, intended to benefit State health departments and the citizens whom they serve.

HEALTH PROMOTION FOR THE ELDERLY

Question. What activities do you support on promoting health and preventing disease among the elderly? What percentage of your budget supports this kind of activity?

Answer. The Office of Disease Prevention and Health Promotion (ODPHP) has the lead responsibility in carrying out the public education portion of the Departmental initiative on health promotion for older Americans. The program is titled "Healthy Older People" and entails television, radio, poster, skill sheet and print advertisement materials, a network of State coordinators in every State appointed by Governors, and linkages with corporate private sector and voluntary organizations.

In addition to this major project, ODPHP has a cooperative agreement with the National Council on Aging to establish a clearinghouse of materials and programs on health promotion for older Americans; the U.S. Preventive Services Task Force is addressing issues specifically related to health of older people as part of its effort to develop age-and sex-specific preventive service recommendations; and ODPHP participates in coordination efforts with the Administration on Aging, the National Institute on Aging, the Health Care Financing Administration and Social Security Administration.

We estimate that approximately 20 percent of the total ODPHP budget supports activities of relevance to the elderly.

NUTRITION

Question. Nutrition is a topic that has received increasing attention. What is your office doing in this area?

Answer. The director of the office serves as chairman of the Department's Nutrition Policy Board, which develops and recommends nutrition-related policy and programs. The Nutrition Initiative of the Office of Disease Prevention and Health Promotion (ODPHP) works to strengthen the Department's capabilities and national leadership in nutrition research, monitoring, services and training, as well as food safety and quality. ODPHP has lead responsibility in developing the first Surgeon General's Report on Nutrition and Health, a 21-chapter report which is being drafted by nutrition experts in various parts of the Public Health Service. In addition to this major project, ODPHP also provides leadership and staff support for the following coordination efforts:

Nutrition monitoring - A Joint Nutrition Monitoring Evaluation Committee, co-chaired by the responsible Assistant Secretaries of the U.S. Department of Agriculture and the Department of Health and Human Services, has been developing a comprehensive report on nutrition surveillance and monitoring scheduled for release in the Spring of 1987.

Nutrition research - The Interagency Committee on Human Nutrition Research, co-chaired by the responsible Assistant Secretaries of U.S. Department of Agriculture and the Department of Health and Human Services, has developed a five-year Federal human nutrition research plan scheduled for release in the Spring of 1987.

Nutrition education - ODPHP sponsors, on behalf of the Department's Nutrition Policy Board, an annual symposium on nutrition, scheduled to coincide with National Nutrition Month in March of each year. This year's symposium will review Federal nutrition research plans.

Question. Are your activities coordinated with other government agencies such as the National Institutes of Health and the Department of Agriculture?

Answer. Yes. Through the Nutrition Policy Board of the Department, chaired by the Director of the Office of Disease Prevention and Health Promotion, continuing close coordination is maintained not only with the National Institutes of Health but also with the Food and Drug Administration, the Centers for Disease Control, the Alcohol, Drug Abuse and Mental Health Administration, and the feeding programs of the Office of Human Development Services. The Joint Nutrition Monitoring Evaluation Committee involves close work with the Department of Agriculture, and the Interagency Committee on Human Nutrition Research, involves coordination not only with the Department of Agriculture but also with the Department of Defense, the AID program, the Veterans Administration, and the National Aeronautics and Space Administration.

HEALTH OBJECTIVES FOR THE NATION

Question. You recently reviewed the objectives for the nation to be achieved by the year 1990. What are these activities?

Answer. The objectives are 227 measurable objectives which were developed in 1980 to help reach five goals for reducing

preventable deaths among those under 65 years of age and unnecessary dependent care for those over 65 years of age. The goals were originally enunciated in Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention. The objectives are arrayed in 15 priority areas which deal with preventive services, health protections, and health behaviors. Each priority area has been assigned to an agency of the Public Health Service to provide leadership and coordination for efforts to achieve the objectives' targets by 1990. Overall coordination and leadership is assigned to the Office of Disease Prevention and Health Promotion. The 15 areas and the agencies to which they are assigned are:

Priority Area	Lead Agency
High Blood Pressure	NIH
Family Planning	OPA/OASH(1)
Pregnancy and Infant Health	HRSA
Immunizations	CDC
Sexually Transmitted Diseases	CDC
Occupational Safety and Health	OASH(2)
Accident Prevention and Injury Control	CDC
Fluoridation and Dental Health	CDC
Surveillance & Control of Infectious Diseases	CDC
Smoking	OSH/OASH(3)

Priority Area	Lead Agency
Misuse of Alcohol and Drugs	ADAMHA
Physical Fitness and Exercise	PCPFS/OASH(4)
Control of Stress and Violent Behavior	ADAMHA

(1) Office of Adolescent Pregnancy Programs, Office of Population Affairs
(2) Senior Advisor for Environmental Affairs
(3) Office on Smoking and Health
(4) President's Council on Physical Fitness and Sports

A sample of the objectives are as follows:

Smoking - By 1990, at least 65 percent of 12 year olds should be able to identify smoking cigarettes with increased risk of serious disease of the heart and lung.

Nutrition - By 1990, 70 percent of adults should be able to identify the major foods which are low in fat content, low in sodium content, high in calories, good sources of fiber.

High blood pressure - By 1990, the average daily sodium ingestion by adults should be reduced at least to the 3-6 gram range.

Physical fitness and exercise - By 1990, the proportion of adults 18-65 participating regularly in vigorous physical exercise should be greater than 60 percent.

Question. How are we doing?

Answer. During 1985, we undertook a midcourse review of the 15 priority areas and the status of each of the 227 objectives. The results of this review are now being prepared for publication later this year. Based on draft reports of the status of each objective, we can tabulate the following statistical profile of their progress to date:

Percent of objectives already met	13%
Percent of objectives on track to be met	32%
Percent of objectives unlikely to be met	25%
Percent of objectives lacking data	28%

Disease - Disease Prevention and Health Promotion

The areas that have demonstrated the most progress are:

High blood pressure
Injury prevention
Infectious diseases
Smoking

The areas that show the least progress are:

Pregnancy and infant health
Family planning
Sexually transmitted diseases
Nutrition
Physical fitness and exercise
Stress and violent behavior

Question. What more should be done to enable our citizens to achieve these objectives?

Answer. From the outset the 1990 health objectives have been promulgated as a set of targets for the whole Nation, depending on all sectors of our society for their achievement. It is clear that progress to achieve those objectives which appear now to be in jeopardy of falling short of our expectations will depend on attention being given to them not only at the Federal level but also by State and local public and private organizations. By publishing the results of the 1985 midcourse review of the objectives, the Office of Disease Prevention and Health Promotion will be able to stimulate some of this needed attention among health policy makers at every level, as well as among health consumers across the Nation. Our plan is to use all forms of communication available to us--publications, conferences, speaking engagements, cooperative agreement projects and other media--and within the bounds of our available resources to focus attention on the areas most in need and the population groups at greatest risk.

PHYSICAL FITNESS - PRIVATE SECTOR SUPPORT

Question. Your budget justification mentions that this program generates financial support from the private sector. How does this program work and how much is generated on an annual basis?

Answer. The Executive Order establishing the responsibility of the President's Council on Physical Fitness and Sports (PCPFS), states that the active support and assistance of civic groups, private enterprise, voluntary organizations, and others shall be enlisted in the efforts to promote and improve the fitness of Americans. The PCPFS works closely with the various physical fitness and sports professional organizations and agencies which carry on programs and professional activities.

Examples of this are cooperative conferences, workshops, and publications with organizations such as the American College of Sports Medicine; U.S. Olympic Committee; American Medical Association; American Alliance for Health, Physical Education, Recreation and Dance; various youth agencies such as the Boy Scouts, YMCA, girls clubs, etc.; and with various corporations. Many proposals are brought to the Council by these entities including various public relation firms representing business, and many of the proposals are presented to these entities by PCPFS staff and/or Council members.

All of these program are carried out on a cooperative basis with no actual exchange of money. It is estimated that approximately $35 million in resources (support and assistance) has been generated annually from the private sector in cooperative programs in physical fitness and sports.

Question. Who are the major private sector participants?

Answer. Sponsors of significant programs include:

ABC Television
ABC Children's Television
Allstate Insurance
Atlas Van Lines
Blue Cross/Blue Shield
CBS Television
Campbell Soup Company
Equitable Assurance Company
Kellogg's
Klein Co., Walter J.
LivingWell, Inc.
McDonald's
NBC Television
Nissen/Universal
Post Cereals
Shedd-Brown, Inc.
Travelers Insurance
Walt Disney Productions

PHYSICAL FITNESS - ELDERLY AND HANDICAPPED

Question. The President's Council on Physical Fitness and Sports in the Office of the Assistant Secretary for Health works with private groups, professional associations, sports groups, and others to promote and improve the health of Americans through regular participation in physical fitness and sports.

What activities does the President's Council support on the physical fitness of the elderly?

Answer. The President's Council on Physical Fitness and Sports is, or has been, involved in several physical fitness activities for the elderly including the following:

In 1985, the PCPFS co-sponsored an international conference on physical activity, aging, and sports conducted with various national and international organizations.

The PCPFS conducts sessions on physical activity for older adults at regional physical fitness and sports clinics, which are training programs for fitness leaders throughout the United States.

The PCPFS is working with the National Association of Area Agencies on Aging and their State offices by providing materials, speakers for meetings, and a joint resolution on fitness for the elderly.

The PCPFS is currently developing plans for a national conference on physical fitness for the elderly. Such a national conference was held in 1981. The proceedings of that earlier program are constantly in demand and have proven to be a stimulating report for activities such as senior State games and area activities on fitness for aging.

The PCPFS develops publications on exercise and fitness for dissemination to the elderly.

Older adult fitness public service advertisements for radio, television and print were prepared and distributed in 1980, 1982, 1984, and 1985.

Question. What physical fitness activities does the President's Council support on behalf of the physically disabled? The mentally disabled?

Answer. The following activities foster physical fitness for the physically and/or mentally disabled:

The PCPFS sponsored a public service television campaign in cooperation with the Veterans Administration in 1985.

Veterans wheelchair competitions in 1985 were co-sponsored with the Veterans Administration and the Paralyzed Veterans of America.

Sessions on physical fitness and sports for the physically disabled are held at each regional physical fitness and sports clinics.

A session is usually conducted at the regional clinics by the Kennedy Foundation and Special Olympics, a sports program for the mentally retarded.

For the past year the PCPFS has been collecting information to assess the physical fitness of disabled youth so that national fitness standards can be established.

The White House Symposium on Physical Fitness and Sports Medicine held approximately every other year includes sessions on fitness research and programming for the disabled.

The PCPFS played a significant role in developing the charter for the Inconvenienced Sportsmen Association which has become the very active National Handicapped Sports and Recreation Association.

PHYSICAL FITNESS - DRUG ABUSE

Question. Does the President's Council have a role to play in dealing with drug abuse among athletes, primarily professional athletes? What would this role be?

Answer. The President's Council has had no responsibility for addressing the subject of drug abuse among athletes. Any role it might take would have to be determined after careful review of responsibilities and authorities of other governemnt agencies with currently assigned participation in this subject.

Questions Submitted by Senator Ted Stevens

USER LIAISON PROGRAM

Question. The User Liaison Program of the National Center for Health Services Research has been very important to Alaska because of its geographic isolation. This program has conducted workshops and seminars, developed research summaries, and provided technical assistance to Alaskan state and local government officials in the health and human services policy area. Has the National Center for Health Services Research studied how elimination of the User Liaison Program would effect states such as Alaska?

Answer. Yes. It would no longer subsidize travel and lodging for Alaska legislators and other State officials. However, it would not impair their access to health services research information because we are developing alternative mechanisms which are less expensive and, I believe, will be equally if not more effective.

Question. What alternate programs are recommended to replace the User Liaison Program?

Answer. A referral and brokering service will be available to State officials seeking information or services from one or more of the 35 academically based health services research centers which now exist. This will rely on in-house NCHSR staff and their contacts in the health services research field rather than on

contractor firms which presently provide consultants to work with State and local officials. This arrangement is too expensive to justify its continuation because of the overhead associated with this mechanism.

We will continue to provide direct technical assistance to States wishing to organize workshops on health services, but we will no longer subsidize the costs directly. We will continue to maintain our in-house dissemination efforts to provide information generated by health services research to State and local officials.

Question. Describe how the User Liaison Program was utilized by state or local officials during the past three years and the costs incurred by the agency in providing such program(s).

Answer. This program has conducted workshops and seminars attended by State and local officials. The total ULP operating budgets for FY 1982 through FY 1985 follows:

FY	AMOUNT
1982	$475,922
1983	836,000
1984	1,099,000
1985	1,199,578

Questions Submitted by Senator Arlen Specter

OFFICE OF MINORITY HEALTH

Question. Assistant Seceretary Macdonald, I was concerned to learn that as late as March 6 of this year, Community Health Centers and Family Planning Agencies in Pennsylvania were not aware that an Office of Minority Health had been established by HHS, or that a director had been appointed. What steps have been taken to educate health care professionals and make the general public aware of the establishment of this new resource?

Answer. The February 28th, 1986 Morbidity and Mortality Weekly Report, a widely disseminated public health publication of the Centers for Disease Control, discussed the Task Force Report as its lead story. It also provided information on how to get a copy of the Task Force Report, which is currently being printed. One of the responsibilities of the Office of Minority Health is to foster state and local conferences on the topic. Conferences have been held in several states and are being planned for others. Dr. Nickens, the Director of the Office, has contacted your staff in response to your concern expressed at the hearing and will be working on strategies to address infant mortality problems in Pennsylvania.

Question. What is the status of the dissemination of the Task

Force Report on Black and Minority Health and now that the report has been completed, how will HHS attempt to close the minority/white health gap, particularly in areas like black infant mortality?

Answer. The executive summary of the Task Force Report is currently available through the Health Information Clearinghouse. The full report is currently being printed. As the report makes clear, we don't have all the answers as to why there is a black/white disparity in infant mortality. DHHS, through the Office of Minority Health and its other programs, will attempt to decrease maternal smoking, increase the proportion of minority women seeking early prenatal care, and decrease teen pregnancy, while fostering research on those problems we do not yet fully understand.

Questions Submitted by Senator William Proxmire

1990 HEALTH OBJECTIVES

Question. Dr. Macdonald, on page 5 of your prepared statement you say: "In 1987, the Office of Disease Prevention and Health Promotion will focus attention on those 1990 Health Objectives for the Nation where further progress is needed." Could you be a bit more precise and tell us where we are falling behind in our efforts to meet the 1990 goals?

Answer. The areas that give us greatest concern, based on the 1985 midcourse review are:

Pregnancy and infant health - We are especially concerned here about recent data showing a leveling out of the previous downward trends in infant mortality rates and incidence of low birth weight infants.

Family planning - This area contains the special challenges related to adolescent pregnancy.

Infectious diseases - A special concern in this area is control of Hepatitis B.

Nutrition - The problems in this priority area appear to be related more to problems in tracking the data than in a lack of progress overall. With the exception of certain at risk parts of American society, we believe real progress is being made but our ability to measure it requires improvement.

Physical fitness and exercise - It appears that our targets in this priority area were much too optimistic. Though progress has been made in making Americans more aware of the health benefits of exercise, translation from public awareness to actual behavioral change appears to be slow, and it seems unlikely that a number of the targets set for 1990 will be achieved.

Stress and violent behavior - We are especially concerned here about homicide and suicide among young people and the incidence of child abuse and other forms of intrafamily violence.

AIDS: RATE OF INFECTION

Question. Dr. Macdonald, in your written testimony you state that an estimated 500,000 to 1 million Americans have been infected by the AIDS virus.

Dr. Fauci told us that about 1 million Americans had been infected by the virus. I would assume from your statement that this estimate could be too high. Is that correct?

Answer. There have been a number of studies undertaken with various methodologies to estimate the number of Americans infected by the AIDS virus, and these studies have yielded a range of estimates. Most current estimates are in the range of 500,000 to 1,500,000. The 1 million figure is in this range.

PHS PHYSICIAN SPECIAL PAY

Question. Dr. Macdonald, last April your Inspector General, after reveiwing the pay and activities of PHS physicians, recommended that you should more effectively collect special pay when Corps or civilian physicians do not complete their contract periods. One suggestion was that special pay be disbursed monthly. Have you taken any steps to effectively collect unearned special pay?

Answer. By law (37 U.S.C. 302(e)), the annual bonus pay of $9,000 or $10,000 for medical officers in the PHS Commissioned Corps must be paid annually at the beginning of the contract period for which payment is made. The Administration submitted a proposal to the Congress as part of the Health Amendments of 1986 which would have authorized payment on a monthly basis, but to date, that proposal has not been enacted.

Through the claims collection staff, PHS works closely with the Department of Justice to take action against civil service employees and commissioned officers who separate from service with a debt to the Federal Government. We will continue to pursue aggressively every legal recourse available.

Question. The same report pointed out that some PHS employees had private practices that had not been approved as required by the Department's Standards of Conduct. Apparently existing controls did not always result in PHS being aware of outside activities. Have you made any efforts to tighten up your control of outside activities?

Answer. Each year PHS civil service employees and commissioned officers are provided with a summary of the regulations governing the Department's Standards of Conduct, with a special emphasis on outside activities. This material is also provided to all new employees and officers. Moreover, supervisors and personnel officers from all PHS Agencies are provided guidance concerning the need for PHS employees and officers to receive prior administrative approval, as delineated in the Department's Standards of Conduct, before engaging in certain outside activities. PHS employees and officers who violate these regulations are subject to severe disciplinary action.

NCHSR CONTINUATION COSTS

Question. I notice that the average cost of a continuation grant or contract under the NCHSR program will increase from $125,000 in 85 to $180,000 in 86 and $304,000 in 87. Can you explain to the Committee why the average cost is going up so rapidly?

Answer. Continuation costs tend to increase significantly in each subsequent year of support. Costs range from about $20,000 for a dissertation grant and upwards of $250,000 to $300,000 for standard project grants. This alone will sufficiently distort an average cost. The average cost of grant and contract continuations as derived, is further distorted by the fact that in FY 1986, a single contract was let for NMES at $2.5 million. The continuation costs for this contract more than doubled in FY 1987 because the survey will be pretested in FY 86 but the full survey will be in the field in FY 87.

Given the size of our research program, and the number of grants/contracts we are able to support, this method of determining average costs is not a valid indicator of trends.

NATIONAL AIDS PUBLIC INFORMATION PROGRAM

Question. Dr. Macdonald, on page 10 of your prepared statement, you refer to a significant expansion of the PHS/OASH comprehensive plan to inform the American public about AIDS. How much will this expansion cost and what form will it take?

Answer. The FY 1987 request of $1,000,000 reflects an increase of $750,000 over the FY 1986 plans. The following describes our National AIDS Public Information Program for FY 1987, including a list of proposed projects for 1987.

NATIONAL AIDS PUBLIC INFORMATION PROGRAM
OFFICE OF PUBLIC AFFAIRS
PUBLIC HEALTH SERVICE

Fiscal Year 1987

OBJECTIVE: To inform the American public about acquired immune deficiency syndrome (AIDS), and other sequelae of infection with the HTLV-III virus, sufficiently to create a widespread awareness and understanding of the nature of these problems, the suspected means of HTLV-III transmission, and the relative threat that HTLV-III infection poses to various populations and to the public health. The aim of this program ultimately is to help prevent and control AIDS and HTLV-III infection by informing the public about specific behaviors to reduce the risk of acquiring and transmitting the virus.

INTRODUCTION

Since publication of the first reports of AIDS cases in 1981, the number of patients with manifestations fitting the Centers for Disease Control's clinical definition of the syndrome has steadily grown. By February 17, 1986, 17,266 cases of AIDS had been reported to CDC, and 9,044 of these patients had died. In addition to these patients with AIDS itself, many more Americans

have contracted AIDS-related illnesses, and an even larger number (perhaps 1 million) have been infected by the HTLV-III virus and can transmit it to others, even though they do not as yet show symptoms of infection.

Today the Public Health Service is bending every effort to develop a vaccine against HTLV-III and therapies that can eliminate this virus from the body and reverse the immune system damage the virus causes. But because a vaccine and effective therapies do not currently exist, effective public information initiatives are vital to bring about behavior change that will reduce the risk of infection with, and transmission of, the virus; to calm unjustified fears; and to create understanding and support of public health guidelines, based on the best scientific information available, to prevent and control the ravages of HTLV-III.

The Public Health Service has devoted a great deal of effort to AIDS public information projects over the past 4 years. At this point a primary need for FY 1987 is sophisticated market research to determine how effective these efforts have been, to identify gaps in public knowledge, and to provide solid information to underpin new strategies for targeting hard-to-reach segments of the public. It is particularly important to have such information on people in the risk groups for AIDS; sex partners (especially heterosexuals) of AIDS patients and people at risk; young people, who potentially represent the next generation of AIDS victims; health care workers; and people in other occupations that put them in close contact with AIDS patients and persons infected by HTLV-III. Moreover, this information needs to be gathered for racial and ethnic subgroups in all these populations.

Another primary need for FY 1987 is a mass media campaign with particular emphasis on young people, who have not been specifically addressed by our previous efforts, and who may place themselves at risk of AIDS by experimentation with IV drug use and casual sex. A special focus of this campaign will be to point out the dangers of casual sex.

The continuing production and distribution of materials containing the latest information on AIDS and HTLV-III infection is vital. Equally important are the daily functions carried out by the PHS Office of Public Affairs and the public affairs offices of the five PHS agencies. These functions include working with reporters on the preparation of accurate stories on AIDS, preparing press releases and other press materials, liaison with other organizations carrying out information and education programs for the public on AIDS, preparation of correspondence with Congress, organizations, and individuals concerned about AIDS, and other similar activities.

Coordination of these diverse efforts by the PHS Office of Public Affairs is essential, as is maintaining up-to-date knowledge of AIDS research and service initiatives being conducted or supported by the PHS agencies.

Following is a list of proposed projects for fiscal year 1987. These projects may be modified as new scientific information becomes available.

PROPOSED AIDS INFORMATION PROJECTS/ACTIVITIES/MATERIALS--FY 1987

1. National coalition.

• Set up and support a national coalition to coordinate and maximize public and private sector communications activities to

inform all segments of the public about AIDS. Cost: $50,000 (additional support from participating groups).

• Through the coalition, sponsor a national conference on AIDS communications to enlist new participants, strengthen the existing liaison, and plan future efforts. Cost: $25,000 (additional support from participating groups).

2. Market Research.

• Carry out, under contract, a thorough study of the level of public knowledge and attitudes about AIDS that currently exist, where that information was acquired, gaps in that knowledge, and effective ways to target hard-to-reach audiences. Develop new information programs and modify current initiatives accordingly. Populations surveyed should include all racial and ethnic groups, and should in particular address the AIDS risk groups; young people, who need to be alerted to the dangers of drug use and casual sex--especially multiple partners--to keep in check the rate of heterosexual spread; sex partners of AIDS patients and persons at risk; health care workers; and workers in other occupations who deal frequently with AIDS patients and others infected by HTLV-III. Cost: $300,000.

3. Initiatives for young people.

• Prepare mass media campaign to get AIDS information to young people, the next generation at risk, and to inform them of the dangers of drug use and casual sex. Cost: $200,000.

• Work with the National Education Association, the American Federation of Teachers, and the National Parent-Teachers Association to develop a 16-mm film on AIDS for teenagers, for school and community use, and a discussion guide for teachers and/or group leaders. Cost: $100,000.

• Contract with the Task Force on AIDS of the American College Health Association to produce and distribute a risk-reduction brochure for students on college campuses. Particular effort should be devoted to ensuring availability of the brochure to students at minority and small institutions that lack funds to purchase such materials. Cost: $10-20,000.

• Contract with the Task Force on AIDS of the American College Health Association for travel by task force representatives to college campuses lacking health education units, to make presentations on AIDS and risk-reduction measures. Cost: $10-20,000.

4. Public information demonstration programs.

• Through the U.S. Conference of Mayors or the Association of State and Territorial Health Officials, support demonstration projects consisting of public affairs campaigns at the local level to inform the public about AIDS, evaluation of these campaigns, and workshops to pass on the knowledge gained from them to other communities. Costs: for campaigns and evaluation, $60-70,000; for workshops, $30,000.

5. Survey of physician knowledge.

• In cooperation with the American Medical Association, sponsor a survey to learn what general practitioners, internists, and other physicians around the country know about AIDS and identify areas where information efforts should be targeted. Cost: $25-50,000.

6. Speakers' bureau to serve local communities.

• Cooperate with the American Medical Association in expanding the bureau of physician speakers on AIDS from the four states (California, Texas, Pennsylvania, and Illinois) where the effort is being initiated in FY 1986 to all 50 states in FY 1987. Cost: $25-50,000.

7. Informing the press.

• Continue to keep the working press updated on AIDS through regular seminars, giving reporters the opportunity to question PHS experts on AIDS. Cost: NA.

• Inform journalism students about AIDS through a contract with Media Resources Center to sponsor workshops on AIDS at 5 leading schools of journalism. Cost: $50,000.

7. Preparing and distributing publications.

• Under contract, continue to develop a mailing key and networking system for efficient and effective distribution of pamphlets and other materials on AIDS to the organizations and individuals who need them. Cost: $100,000.

• Continue to update AIDS information materials. Develop new materials targeted to young people and to women who are sex partners of persons infected with HTLV-III or at high risk of infection. Cost: included in the above.

• Enlist the aid of writers and editors of women's publications in getting needed, realistic information to women about the possibilities of infection with HTLV-III and potential consequences regarding perinatal transmission of the virus. Cost: NA.

TOTAL COST: $985,000 - $1,065,000

AVERAGE GS GRADE

Question. I note that your average GS grade continues to creep upward. Your 1985 justifications indicated you expected your average GS grade to be 10.19 in fiscal 1985. Your 1986 justifications revised that figure upward to an estimated average grade of 10.30 in fiscal 1985. Your 1987 justification shows that your average grade in 1985 was actually 10.53 -- a far cry from the 10.19 you initially projected.

Why was your first estimate so wide of the mark?

Answer. OASH remains in a relatively static employment situation in which attrition has occurred primarily in the lower grades. As a result, the average grade for OASH as a whole has not been lowered.

Questions Submitted by Senator Patrick J. Leahy

USER LIAISON PROGRAM

Mr. Chairman, It has come to my attention that the User Liaison Program of the National Center for Health Services Research (NCHSR) in the Department of Health and Human Services, is targeted

to take the brunt of the 4.3 percent agency budget cut under the Gramm-Rudman-Hollings legislation.

For the past eight years, the User Liaison Program has been conducting workshops and seminars, developing research summaries, and providing technical assistance to state and local government officials, including members of state legislatures, appointed representatives of government agencies, and others with decision-making responsibilities in the health policy area.

The major objective of this program has been to enhance the knowledge and understanding of such senior policy makers on critical health and human services issues, and to assist them in applying the knowledge base to particular local, state and regional problems. As you know, these groups play a major role in carrying out federal policy initiatives and in developing appropriate responses to identified state and local needs.

Often, those who must make these vitally important policy decisions do not have a background in health and human services. In addition, they rarely have professional staff to assist them in these issues. At a time when the federal government is reducing its financial support to states and communities for health, education and human services, I question whether the decision to virtually wipe out the User Liaison Program is a wise one.

It seems reasonable and beneficial to carry out such workshops, seminars and technical assistance activities as a cost-effective means of realizing the positive outcomes of the federal investment in research.

I have heard from a number of concerned state and local officials in Vermont about this. I understand that many Senate offices have received similar statements of concern from senior officials in their states.

I want to say publicly that I appreciate the cooperation of Dr. John Marshall, Director of the National Center for Health Services Research, for his courteous and prompt response to questions asked by staff, at my request.

However, I am disturbed about several aspects of Dr. Marshall's decision to take a "disproportionate cut," as he himself termed it, from the User Liaison Program, as a means of implementing the 4.3 percent cut which his agency sustained under Gramm-Rudman-Hollings. Apart from whether Dr. Marshall's rationale regarding program priorities can be supported, I question whether the authority under the legislation allows such an action.

I voted for the Gramm-Rudman-Hollings act because, apart from my concern about the federal deficit, I believe it offers Congress and the Administration a chance to get our priorities in order.

It may be, that after full consideration of this matter, Dr. Marshall has indeed made a wise decision. Until that is made clear, however, I wonder if it might not be a more fair and less destructive approach, to evenly distribute the approximate $707,000 cut, which I believe is the agency's share, across-the-board rather

than take $635,000 or 90 percent of the total reduction, from the User Liaison Program.

Mr. Chairman, in this connection, I would appreciate receiving a response to the following questions:

The Gramm-Rudman-Hollings Act required NCHSR to reduce its appropriated FY 1986 budget by 4.3 percent, or $707,000.

GRAMM-RUDMAN-HOLLINGS REDUCTION

Question. How much of this reduction was taken from the FY 1986 User Liaison Program budget? What percentage of the $707,000 does this represent?

Answer. Prior to the passage of Gramm-Rudman-Hollings, NCHSR had already reduced the amount of money available to the User Liaison Program. However the User Liaison Program was judged to be in need of further restructuring given the requirements of Gramm-Rudman-Hollings.

Six hundred thirty seven thousand dollars or 90% of the $707,000 was taken from the User Liaison Program in FY 1986.

Question. What amount and percentage of the reduction was taken from the following other components of the National Center to meet the mandated cuts of $707,000: the Division of Intramural Research; the Division of Extramural Research; and the Division of Research Dissemination and External Liaison?

Answer. The allocation of the $707,000 reduction was designed to minimize the impact on the research program of the National Center. Therefore, the mandated cuts were not specifically applied to either the Division of Extramural Research or the Division of Intramural Research. Neither was a specific reduction applied to the Division of Research Dissemination and External Liaison. The remaining $70,000 reduction was taken in the program support activity and was achieved by delaying equipment purchases, revising the FY 1986 travel plans, and delays in filling vacant positions where they existed within NCHSR.

Question. By what amount and by what percentage was the budget of the Office of the Director reduced to meet the mandated cuts?

Answer. There was no reduction applied to the Office of the Director. The Office of the Director includes only the director and a secretary. There are no program funds in the Office of the Director.

CONSULTATION WITH STATE OFFICIALS

Question. During the period in which the decision was made to eliminate the workshop, seminar and technical assistance activities of the User Liaison Program, did NCHSR consult with senior state and local officials who have participated in this Program in order to obtain and assess their views on the impact of the decision upon them and the health care delivery and financing programs and

policies for which they are responsible? I ask this because I am aware of the concern this decision has generated among high level officials in a number of states.

Answer. No. The Director was well aware of the enthusiasm with which State and local participants in the User Liaison Program held the opportunity they had to participate in the workshops. The decision to restructure the User Liaison Program was not made because the program is unpopular. Neither was it made because the Center does not believe the research dissemination is important. The need to develop more cost-effective alternative mechanisms was driven by the relatively high cost of ULP activities.

ULP-TRAVEL FUNDS

Question. I have heard conflicting reports of the amount of User Liaison Program funds utilized for the travel of state and local officials to workshops and seminars. Some figures are as high as 90 percent.

What is the percent of total User Liaison Program contract funds expended in FY 1985 for travel of officials to workshops and seminars, including the costs of food and lodging in this figure?

Answer. In FY 1985 approximately 11% of the User Liaison Program contract funds were expended for the travel, meals, and lodging of State and local officials attending seminars/workshops.

Question. What is the percentage of the total FY 1985 contract funds expended for all other travel paid for by User Liaison Program contractors?

Answer. In FY 1985 approximately 11% of the User Liaison Program contract funds were expended for all other travel, meals, and lodging.

Question. In a communication with Ms. Pearl Somaini-Dayer of my staff, received on February 18, Dr. Marshall referred to an "analysis of the budget...of the contractor program" which showed "that over 60 percent of the administrative (sic) budget" was spent "for transportation, hotels, subsistence and contractor overhead/profit." In other communications, he cites travel, subsistence or meals, and housing or hotels, as the first items of which this 60 percent consists. This infers that travel, housing and subsistence represent a major or dominant portion of the 60 percent figure. What percentage of the 60 percent represents travel, housing and subsistence?

Answer. In FY 1985 approximately 37% of the funds ($204,871) represented by the 60% figure were expended for travel, meals, and lodging. I would emphasize that Dr. Marshall's letter referred not to the administrative budget but to the total budget.

Question. Committee staff have been advised by state officials that the User Liaison Program makes a concerted effort, as part of their policy, to get state and local officials to pay all or a portion of their travel expenses to workshops and seminars. I would like to know whether, during the past 18 months,

state and or local officials from Connecticut, Hawaii, Vermont, New Hampshire, Kentucky, Mississippi, Washington, Wisconsin, Texas and Massachusetts have been paid for all or a portion of their travel.

Answer. Some officials from the States which you list have paid for all or a portion of their travel. Participant travel has been totally subsidized by Federal funding in whole or in part by other participants from: Alabama, California, Colorado, Connecticut, Florida, Georgia, Hawaii, Idaho, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin.

Question. At the last major workshop held by the User Liaison Program in Rensselearville, New York last October, how many of the 26 participants paid all or a portion of the travel expenses?

Answer. Non-Federal funds were used to pay air fare for 2 participants. One was from Kentucky and one was from Mississippi. Non-Federal funds were used to upgrade fares from tourist class to first class for two participants from Hawaii.

From NCHSR's perspective, the important issue is the cost of the October workshop for these 26 participants. The contractor charged $163,000 which averages to an individual cost of $6,269.23 per participant or $1,140 per day.

Question. I understand that the User Liaison Program asks participants to certify in writing that their respective legislature or government agency does not have funds to pay for their airfare to the workshop prior to authorizing their contract to issue an airline ticket for such transportation. Is this true?

Answer. Yes. It has been true for approximately 18 months since the NCHSR Director established that policy.

Question. In the course of gathering information about the User Liaison Program, a member of my staff, Ms. Pearl Somaini-Dayer, spoke by telephone to the Director of National Center for Health Services Research, Dr. John Marshall. At her request, Dr. Marshall put his comments in a letter to her, received in my office on February 18, 1986. Following is an excerpt from Dr. Marshall's letter.

> In November, I learned of an activity undertaken by the User Liaison Program which was clearly at the margin of what is appropriate. User Liaison funds had been used to pay a consultant from Brandeis University who spent appropriately one month developing, for the legislature, an evaluation of the administration of the State Maternal and Child Health Program. A special report was prepared for the legislature. Further, User Liaison funds were used to provide support for a member of the legislative staff who assisted with the report. I consider this to be an inappropriate federal intervention between the legislative and executive branches in the State of Vermont. Further, the Director of the User Liaison Program,

Mr. Robert Fordham, informs colleagues that he has close personal ties in Vermont. He has been an employee of the State of Vermont. He has many friends in the legislature, and in the Executive Branch. He does not have an arms length relationship with the political and administrative hierarchy in the State of Vermont. He conducts a disproportionate amount of ULP business in Vermont.

Mr. Chairman, I do not believe I need to stress to you how concerned I am both about the seriousness of the allegations leveled by Dr. Marshall and about the facts that they reflect badly on unnamed Vermont State officials. Moreover, I'm extremely disturbed by the fact that of this date, they are unsubstantiated.

The questions I pose to Dr. Marshall are as follows:

ULP ACTIVITIES IN VERMONT

Question. You allege that the federal official involved in this activity, Mr. Fordham, "does not have an arms length relationship with the political and administrative hierarchy in the State of Vermont." Please explain what this means.

Answer. Over the three years during which Mr. Fordham has worked as an employee of the National Center for the current Director, he has commented on several occasions about his close personal relationships with elective and appointed officials in the State of Vermont.

Question. In the cases you identify in which Vermont officials were engaged in a less than "arms length relationship" with the federal officials involved, please explain what this means.

Answer. Mr. Fordham has indicated that he has personal and social relationships with these individuals which predate his employment at the National Center.

Question. You allege that "User Liaison Program funds were used to provide support for a member of the legislative staff" of the Vermont State Legislature. Who, and in what capacity? What amount of money was paid this individual?

Answer. Marcia Marshall (who is not related to Dr. Marshall the NCHSR Director), an employee of the State Legislature when it is in session, was paid $100 per day for 15 days to assist a consultant from Brandeis University.

Question. You allege that in some way Mr. Fordham's actions in connection with a project being undertaken in collaboration with the Vermont State Senate Health and Welfare Committee represents "an inappropriate federal intervention between the legislative and the executive branches in the State of Vermont." Please define the term "inappropriate federal intervention" and tell me just what you mean. Who within the executive or legislative branch of the State of Vermont either participated in or was aware of this alleged "inappropriate federal intervention"?

Answer. The Director of NCHSR determined that it was inappropriate for NCHSR funds to be used to assist the legislative body in the State of Vermont to design an evaluation of the impact of a specific program in one State outside of the normal competitive processes and not subject to scientific review. This activity was clearly beyond the scope of the normal program activities of NCHSR. Since the Director was responsible for making this decision, and did so, whether anyone in the executive or legislative branch of the State of Vermont participated in or was aware of this inappropriate Federal intervention is not germane.

Question. You claim to have received a complaint from someone in Vermont concerning the alleged "inappropriate federal intervention." Please provide evidence of this.

Answer. No one from Vermont alleged that this was inappropriate Federal intervention. The Center Director was asked whether he was aware of this activity and whether he approved of it. He investigated and determined that Federal funds were used to pay for Dr. Kurtz's and Ms. Marshall's work. The NCHSR Director determined that this was inappropriate.

Question. Also, I am curious to know whether Mr. Fordham was notified by you or any other responsible federal official at any time that such alleged "inappropriate federal intervention" was or had been charged.

Answer. Mr. Fordham was informed by the Center Director that this was considered to have been an inappropriate use of funds allocated to the User Liaison Program. He directed Mr. Fordham, in November of 1985, to assure him that User Liaison funds would not be so used in the future.

Question. You mention Mr. Fordham's previous employment in Vermont. Please provide me with specific information on the nature of Mr. Fordham's previous employment as a Vermont State official. How is that experience germane to the allegations you advance in the February 18 letter?

Answer. Mr. Fordham was an employee of the University of Vermont, reporting to the Vice President or President from 1967 to 1972. Mr. Fordham has indicated to Dr. Marshall his close personal ties with individuals in Vermont.

Question. In the course of reaching the conclusions stated in your letter, particularly the assertion that an "inappropriate federal intervention between the legislative and executive branches in the State of Vermont" had occurred, did you communicate in any way with the Chairperson of the Vermont State Senate Health and Welfare Committee, former Governor Philip Hoff, in an effort to obtain his views on this matter? Did you communicate in any way with the Secretary of the Vermont Agency of Human Services, Gretchen Morse, the Commissioner of the Vermont Health Department, Dr. Roberta Coffin, or Governor Medeline Kunin to ascertain their views on this alleged "inappropriate federal intervention" prior to making the allegations contained in your letter to Ms. Somalni-Dayer? Also, did you make inquiries to Dr. Norman Kurtz regarding the facts of this matter? In the event you did communicate with any of the above individuals regarding this matter, please provide

copies of the correspondence or memos of record of the conversations that took place.

Answer. It was the Center Director who determined that this was an inappropriate use of NCHSR funds. That assessment was based on review of the Task Order for the contract from which Dr. Kurtz was paid.

Question. Since the nature and audience for which the document prepared by Dr. Kurtz was and is an important factor in your allegations, would you provide the following additional information related to his document:

Have you read this document? If so, from which federal or state officials did you secure the report and on what date?

Answer. Dr. Marshall has read Dr. Kurtz' document. The report was available to Dr. Marshall from the Federal Contract files.

Question. The document prepared by Dr. Kurtz and submitted to the Vermont State Health and Welfare Committee, and provided to my office by Vermont State officials, in my view reveals that it was not "an evaluation of the administration of the State Maternal Child Health Program", but rather, to quote from its introduction: "The purpose of this report is to provide a summary of the potential for developing an evaluation of the effectiveness of maternal, child and handicapped children's services. While the actual development of an evaluation design goes beyond the scope of this report, the goal here is to identify a framework around which such an evaluation could be organized, describe current activities relevant to such an evaluation, and essential data required for assessing the systems of service." Please provide your explanation for referring to it as "an evaluation" in both your oral and written communications with my staff.

Answer. The issue is not that a design would be appropriate while an evaluation was not. The problem was in providing a service to Vermont which was not announced as being available to other States.

Question. You stated that a special report (as distinct from the report Dr. Kurtz was to prepare) was "prepared for the legislature." Please provide me with a copy of this "special report" and the date it was transmitted (or is scheduled to be transmitted) to "the legislature." Who was the author of this report and what amount of funds were provided by the User Liaison Program to this individual?

Answer. The special report refers to Dr. Kurtz's report to the legislative committee. Dr. Kurtz received $1,800 and Ms. Marshall received $1,500. The contractor overhead was an additional $693.

Question. At any time were any or all of the allegations contained in the letter in question conveyed either in writing or verbally to any individuals other than Ms. Somaini-Dayer, including NCHSR staff, Vermont State officials or either the legislative or executive branches, or private citizens outside the State of

Vermont? If so, please describe the nature, context and content of such written or oral communications.

Answer. The statements made by Dr. Marshall were shared with those NCHSR and Public Health Service staff who had a need to know. This information was not shared with any Vermont State officials by Dr. Marshall.

Question. What percentage of the FY 1985 User Liaison Program contractual expenditures were for projects requested by Vermont state officials?

Answer. In FY 1985, approximately 3 percent of User Liaison Program funds were expended for projects requested by Vermont officials. The issue that concerned Dr. Marshall was not the extent to which the State of Vermont was benefiting, but the extent to which Mr. Fordham's frequent travel to Vermont and his special treatment by providing special technical assistance through Dr. Kurtz and Ms. Marshall, might create an appearance of inequity since the Center has not provided this type of technical assistance for other States. For example, Mr. Fordham made 35 trips on official travel orders in FY 1985. Eight of those were to Vermont. Two of five travel orders thus far in FY 1986 involved travel to Vermont. When your office requested information, Dr. Marshall attempted to be frank and candid with Ms. Somaini-Dayer. When she called several days later and asked him to provide a written record of their discussion, he did so freely and promptly. Dr. Marshall was trying to make the point that Mr. Fordham's behavior gave an appearance of favoritism toward Vermont. He wanted the Senator's office to be aware of that as well as to be aware of the fact that he had brought it to Mr. Fordham's attention.

Mr. Chairman, I would appreciate a response to these particular questions as soon as possible.

I want the record cleared at once as to whether Vermont has in any way benefitted inappropriately from the User Liaison Program.

Thank you for the courtesy of allowing me to join in your Subcommittee's review of the NCHSR.

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF DR. JAMES B. WYNGAARDEN, DIRECTOR

FUNDING OF GRANTS

Senator WEICKER. Before we get to the Institutes, I have a few questions that I would like to discuss with you. I have a couple of things that I want to get responses on.

During my tenure as chairman, as you know, I have placed a great deal of emphasis on the number of grants. I have managed to get the press focused on it, and I have been able to get my friends in the House focused on it, and I am focused on it. Interestingly enough, I don't only ask you fellows questions, but I am asking myself questions.

The question I have is this: Relative to intramural research, training, clinical trials, equipment, and construction, are we funding grants at the expense of these other things?

Have I gone overboard, in other words, in the sense that these other matters are going to suffer because of the focus on grants, and if grants are OK, everything else is OK at NIH, I suppose that is the question that I am asking.

Maybe in my zealousness on this cause, other things are suffering, which really are as important or maybe the basics to support the whole grant concept.

RESEARCH GRANTS

Dr. WYNGAARDEN. The only point that I would make is that we consider investigator-initiated research project grants as the highest priority mechanism that we have for supporting research, and that, naturally, leads to our focus on grants and the number of grants, the average cost of grants, and the award rates.

There is no question that research project grants are not the only mechanism available for the support of research. If we had nothing but grants, I think that we would clearly be impoverishing the system.

Training is important. Clinical trials are important. All the things that you have mentioned are important. We have shifted funds into the research project grants annually for many years, from around 37 percent in 1974 to 56 percent in 1987.

I think that the majority of the Institute directors feel that compressing the other mechanisms beyond that percentage does begin to distort the entire display of program mechanisms that we employ. Training, at present, is 4 percent of our budget. That is the lowest that it has been in some time.

INTRAMURAL RESEARCH

Senator WEICKER. What about your intramural research?

Dr. WYNGAARDEN. The Intramural Research Program averages about 11 to 12 percent of the budget. Within the grant mechanism, the equipment category has declined slightly because of the competition and the increasing cost of personnel. So we have to keep an eye on the distribution within the grants, and also within the intramural program.

We have tried, in general, to present the needs of the intramural program in the budget presented each year, and I think we have done that again this year. These areas are tighter than they have been, and I continue to think that the concern about the number of grants and the cost of grants is a very important and major concern, but we must not lose sight of the fact that we have clinical trials that are important, requiring contract support to augment the grant activities that go on every year.

You mentioned construction; we have not asked for construction funds in order to protect our higher priority areas.

NIH EMPLOYMENT

Senator WEICKER. How many people are employed by NIH now compared to 4 years ago?

Dr. WYNGAARDEN. The current onboard strength as of February 1986 was 13,062 full-time permanent and other than full-time permanent employees who count against FTE ceilings, compared to 12,969 in February 1982.

CONSTRUCTION

Senator WEICKER. The matter of construction, and you may supply, for the record, your estimates of the capital needs for the present and future biomedical needs.

Three years ago, NIH was asked to do a report on the needs of construction for NIH funded programs. Do we have such a report?

Dr. WYNGAARDEN. We have not received OMB clearance to conduct the necessary survey. However, some current estimates are that the research institutes require $1.3 billion annually.

Senator WEICKER. Have we implemented the recommendations of that report?

Dr. WYNGAARDEN. We have done some informal surveys.

Senator WEICKER. As I recall, didn't you give a major speech on this business of the infrastructure and construction early on in your tenure?

Dr. WYNGAARDEN. Yes; our estimates are around the several billion dollar range, the shortfall for construction, for new construction and for remodeling in the scientific enterprise as a whole, and that has been addressed primarily by Congressman Brown's committee in looking at science needs in general.

We don't have a precise figure on it. We did a sampling of some schools. There is a major unmet need. We, of course, have authority for extramural construction in only three Institutes. The general authority

expired in about 1974, and the funding in 1967. So we currently have authority only in the Cancer Institute, the Heart Institute, and the Eye Institute. We have had small sums for construction in recent years. For example, the amount appropriated in fiscal year 1986 was $13.1 million.

PERTUSSIS VACCINE

Senator WEICKER. My last question, which was brought to my attention, is the matter of the pertussis vaccine problem. It is my understanding that Lederle is the only American manufacturer. There is a Canadian manufacturer, but who cannot meet our needs here in the United States. The liability problem attached to Lederle and this vaccine is basically that they might be placed in a position where they will no longer issue it.

I gather, No. 1, the vaccine ought to be improved. That is my first question, what we are doing on that score. No. 2, are we going to have a vaccine in the forthcoming year?

Dr. WYNGAARDEN. There are a number of developments in the area of pertussis vaccine development and testing that are moving along quite well; in particular, a new acellular pertussis vaccine made from just one highly purified component, the inactivated toxin, has been developed by a scientist in the National Institute of Child Health and Human Development. This vaccine will soon be ready for the beginning stages of clinical testing in Sweden, where the old DPT vaccine has not been used for some years, resulting in an epidemic of whooping cough. There are also plans being developed to test the NIH vaccine in the United States at an early time.

There is no doubt that the old DPT vaccine has an unacceptable rate of side effects, and infrequently very serious toxicity, but still the risk of serious side effects is 100 or 200 times less than the risk of serious consequences from pertussis in the unvaccinated population. So DPT is an effective vaccine, but it has an unacceptable percentage of serious reactions.

There is also a new Japanese vaccine that is in the testing stage in a different area of Sweden. We must test these vaccines in populations where the incidence of pertussis is higher than in the United States to develop efficacy data. However, side-effect data will have to be developed in the United States since we'll need very large numbers of vaccinated people to be sure that the relatively low incidence of serious side effects from the old vaccine has been reduced significantly with the new vaccines.

Senator WEICKER. Can we use the present supply of Lederle vaccine? What is going to happen within the next year?

Dr. WYNGAARDEN. I believe Dr. Alexander, Director of the NICHD, can answer that question.

Dr. ALEXANDER. The Lederle issue will come to a head this July when their liability insurance must be renewed. We are hopeful that they will continue to produce the vaccine. The recommendations from the American Academy of Pediatrics, and the Public Health Service, are

that the present vaccine ought to continue in use until such time as an improved vaccine is available.

Senator WEICKER. Dr. Alexander, when is pertussis vaccine given in relation to being effective against the prime time for the disease? When would a new pertussis vaccine be administered?

Dr. ALEXANDER. The DPT vaccination is given usually at 6 to 8 weeks of age. It is given in three initial shots in the first year, and a booster shot thereafter. Those are the standard recommendations. The peak time of risk for pertussis is in infancy, so it is important that these immunizations be given very early.

Senator WEICKER. Can you foresee a situation, let's say, on August 1, where we are not going to have any DPT vaccination going on for a period of time?

Dr. ALEXANDER. The Public Health Service has a stockpile of vaccine that it maintains at the Centers for Disease Control. I don't know what the duration of that stockpile of vaccine is. If Lederle should decide to discontinue distribution of the vaccine this summer, there would not be an immediate crisis because of the availability of the existing supplies plus the stockpile and there would be some time in which other arrangements could be made such as obtaining increased supplies from Canada.

Senator WEICKER. At the earliest, when would these new vaccines be available for public use?

Japanese, American, or whatever it is, I don't care, at the earliest, when would the new vaccines become available for public use?

Dr. ALEXANDER. From the trials that are going on in Sweden, we won't know about long-range efficacy or safety for at least a couple of years. So if you are talking about the crisis that may come up in August, even with the Public Health Service's stockpile there is going to be a problem time wise.

Dr. WYNGAARDEN. PHS maintains a stockpile, and I believe the goal is to maintain an 8-month stockpile. I think they are a little short of that, but not a whole lot, about 5 or 6 months is my understanding.

Senator WEICKER. I think, without pursuing this any further, that you and I should have a conversation as to exactly where we stand on this matter because, obviously, there is some urgency.

Dr. WYNGAARDEN. The liability problem is, of course, a general one. It is highlighted by pertussis, but it is an issue that needs to be addressed in terms of the AIDS vaccines, too. It is a factor that deters American companies from getting as active in these projects as they should be.

NATIONAL INSTITUTES OF HEALTH

NATIONAL INSTITUTE OF DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

STATEMENT OF DR. PIERRE RENAULT, ACTING DIRECTOR
ACCOMPANIED BY EARL LAURENCE, EXECUTIVE OFFICER

INTRODUCTION OF ASSOCIATE

Senator WEICKER. Dr. Renault, good to have you. Why don't you go ahead and submit your statement for the record, synopsize it, and we can get to the questions.

Dr. RENAULT. Thank you, Mr. Chairman. I am pleased to be here to report on the National Institute of Diabetes, and Digestive and Kidney Diseases. I am accompanied by our Executive Officer, Mr. Earl Laurence. I would like to make a few comments highlighting my written statement.

NIDDK supports a diverse, but comprehensive program of research on some of our Nation's most severe and debilitating chronic diseases. We support and conduct research in diabetes, endocrine, and metabolic diseases, in digestive diseases, and nutritional disorders, and in kidney, urologic, and blood diseases.

In the area of diabetes, in the last year, we have initiated a full-scale clinical trial, testing the hypothesis that keeping a diabetic patient's blood sugar as close to normal as possible will prevent the development of the complications of diabetes.

This trial, the diabetes control and complications trial, will involve 1,400 patients in 26 treatment centers around the Nation. With this trial, we expect to answer one of the most fundamental issues in the treatment of diabetes. We also expect it to have a major impact on the treatment of diabetes in the United States.

In metabolic diseases, you have already heard about the discovery of the genetic marker for the cystic fibrosis gene. This will aid greatly in finding the cause, and hopefully the cure, of this disease.

In digestive diseases, we have begun work on a liver transplantation data system. Liver transplantation is a procedure that cannot be studied with a randomized clinical trial, at least not as a whole procedure. A liver transplantation data system will enable transplant surgery teams to systematically collect information on the patients they treat and thereby learn from their experience and the experience of others.

Most of the liver transplantation units around the Nation have voluntarily participated in the planning of this system, indicating the im-

portance they feel this information may have on improving our ability to do successful liver transplantations.

In kidney diseases, we have another example of molecular genetics. The gene associated with polycystic kidney disease has been located. This disease is a major cause of end-stage renal disease, and we hope that finding this gene will lead to an effective treatment for the disease. But it has immediate implications for families who are afflicted with this disorder. It is a disorder that doesn't become manifest until adulthood. Now individuals can be identified before the disease becomes manifest. In the past, families had to live with the unknown, essentially. Now, those who are afflicted and those who are not afflicted can be found. Interventions for those who are afflicted are also possible, to try to prevent the development of the cysts.

Finally, the Institute now has underway, in collaboration with the Health Care Financing Administration, the pilot phase of a major multicenter clinical trial of a nutritional intervention in chronic renal disease. There is considerable evidence that dietary protein can have a deleterious effect on kidneys that have been damaged by disease. Waste products of the metabolism of protein increase the blood pressure and flow in the blood filtering units of the kidney beyond their natural capacity, causing their deterioration, and thus the progressive loss of renal function. The restriction of dietary protein early in the course of chronic renal disease may actually prevent the progression to end-stage renal disease, and the need for renal dialysis.

Mr. Chairman, the 1987 budget request for this Institute is $418,971,000.

PREPARED STATEMENT

This concludes my remarks, and I would be happy to answer your questions.

[The statement follows:]

Statement of Dr. Pierre Renault

As the Acting Director of this Institute, I appreciate the opportunity of discussing with you some of the plans and accomplishments of our extramural grantees and intramural scientists. Our Institute has served as a leader for over 30 years of a broad research effort on some of our nation's most serious and debilitating diseases: diabetes, endocrine, and metabolic diseases; digestive diseases and nutritional disorders; and kidney, urologic, and blood diseases. While progress in knowledge and treatment of these diseases has been steady, in-depth understanding of the causes and progression of these diseases has attended the mobilization of the powerful techniques of modern biomedical research. As a result of NIDDK's intensive investment in basic research, we now have models of the probable sequence of events leading to many of these diseases. I am pleased to be able to present examples of how advances in basic research have progressed in tandem with development of new methods of diagnosis, treatment, and prevention of disease.

Diabetes, Endocrinology and Metabolic Diseases: Progress at the frontiers of medicine is amply evident in research on diabetes, estimated to affect 11 million Americans at a cost of $14 billion annually. Evidence is continually expanding on the aberrant immune response which causes destruction of pancreatic islet cells and therefore loss of insulin-producing capacity in insulin-dependent diabetics. Testing these findings, researchers have demonstrated that a transfusion of peripheral or splenic lymphocytes is able to prevent the development of the disease in diabetes-prone animals. The protective effect of this transfusion lasted for over a year in some cases.

Application of immunologic findings will also determine the success of transplantation of pancreatic islet cells, which holds the promise of restoring near-normal insulin production to individuals with insulin-dependent diabetes. The Institute is supporting efforts to adapt for use in diabetes patients a technique of islet cell grafting which studies in animals suggest may be effective, even in the absence of prolonged immunosuppression.

While the daily existence of an insulin-dependent diabetic may prove restrictive and difficult, it is the complications of diabetes which are devastating and often prematurely fatal. The Institute's Diabetes Control and Complications Trial, designed to determine whether strict control of blood glucose levels can prevent or ameliorate vascular and other long-term complications of diabetes, entered the large scale phase in fiscal year 1986. This phase of the trial will monitor 1,400 patients for five to seven years, and is expected to produce results which may have a major impact on the clinical management of diabetes for many years to come.

The Institute also conducts in its intramural facility in Phoenix, Arizona, a valuable program of epidemiologic and clinical research on the Pima Indian population, a unique, almost genetically pure population which has the highest rate of noninsulin-dependent diabetes in the world. More than twenty years of study has resulted in a wealth of important insights into this disease, including the discovery of a genetic marker which correlates with increased risk of developing diabetes. Researchers hope to use this marker to

locate the gene or gene sequence that contributes to the increased predisposition to diabetes in the Pima Indians. In addition, the Institute plans to initiate shortly in this population a multifaceted study of renal disease, diabetic nephropathy, the major cause of death in diabetic Pimas.

The Institute has maintained a long history of leadership in basic and clinical research on endocrine and metabolic disorders. Recombinant DNA techniques have already made possible the synthesis of potentially unlimited amounts of clinically effective insulin, somatostatin, and growth hormone. Institute grantees have recently synthesized growth hormone releasing factor or GRF, a neuropeptide which stimulates the pituitary to produce and release growth hormone. Clinical tests of synthetic GRF showed that it can achieve, in patients with a primary deficiency of this factor, an increase in growth comparable to that seen with growth hormone therapy, but with an approach which promises to be safer, less costly, and more easily administered. An array of potential new therapies are expected to emerge as researchers characterize the physiologic roles in health and disease of other important hormones and determine their genetic blueprints.

Although inherited metabolic disorders are individually uncommon--many are considered "orphan diseases"--approximately 30 to 40 percent of all admissions to children's hospitals and approximately one-third of all infant deaths in the U.S. are attributable to such disorders. Advances in molecular biology and genetics have brought us to the threshold of combating specific inherited metabolic diseases, such as Lesch-Nyhan syndrome, through gene replacement. Each year, such intensive research efforts bring us closer to uncovering the basic metabolic defects in cystic fibrosis (CF), the most common lethal genetic disease in Caucasians. Recently, the Institute has assembled a talented group of intramural investigators and significantly expanded its support of CF research. These intramural scientists have successfully applied a technique, now under further testing, which promises to provide a superior indicator of disease and clinical status in patients with CF. This year has also witnessed the discovery of three markers for the CF gene. While not responsible for CF, these genetic markers have revealed that the CF gene is located on chromosome 7, and their discovery has vastly narrowed the search for the gene responsible for CF.

Digestive Diseases and Nutrition: Digestive diseases rank second only to cardiovascular diseases as the leading cause of disability due to illness in the U.S. These diseases include more than 40 acute and chronic gastrointestinal conditions, burdening our country with costs estimated as high as $50 billion per year. The Institute is encouraging the application of innovative techniques of molecular biology, immunology, and biomedical engineering to understanding, treating, and eventually preventing these illnesses.

A wealth of new findings has been applied to reducing the toll of these diseases. Gallstones, present in 10 percent of the population, can now, in some cases, be treated on an outpatient basis. In the most recent such non-surgical procedure devised, an Institute grantee successfully dissolved gallstones in patients using a solvent called methyl tertiary butyl ether, or MTBE, administered trans-abdominally through a catheter under local

anesthesia. Such an alternative to abdominal surgery holds the promise of enormous cost savings and increased safety, especially in individuals at high risk, and far more rapid return to normal activity than is possible now.

New medications and surgical techniques have reduced the number of peptic ulcer patients requiring hospitalization for treatment of their condition by more than 40 percent between 1970 and 1980. NIDDK intramural investigators have obtained positive results in preliminary testing of two additional drugs to treat this disease. Unprecedented progress in preventing and treating ulcers and other digestive diseases may also result from the recent discovery of hormones, usually neuroregulatory peptides, in both the brain and in the digestive tract or its nervous system. These hormones may prove to be the sought-for links between stress factors, the nervous system, and digestive tract function. Using modern molecular biologic techniques, investigators will identify, characterize, and eventually synthesize these substances, investigate their activities, and apply them to therapeutic intervention.

NIDDK's intramural and extramural nutrition research programs underpin research throughout our Institute and NIH. Through basic metabolic and clinical studies, this program is tackling the myriad questions regarding human diet in the maintenance of health and the prevention and management of a wide range of diseases. The Institute's intramural program has contributed greatly to the recent exponential increase in understanding of vitamin D disorders. High priority areas of research will continue to include calcium and vitamin D metabolism, the metabolic and health consequences of polyunsaturated fatty acids, and the development of new techniques of nutritional assessment. NIDDK's continuing assessment of the diet of patients receiving total parenteral nutrition will both improve the effectiveness of this therapy and refine our understanding of human nutritional needs.

Another objective of this program is the control of obesity, a major problem in our society. The recently-reported study of adoptees, which proved definitively that genetic factors, not family environment, determine human fatness or thinness, was partly supported by NIDDK. By narrowing the scope of the population vulnerable to obesity, the results of this study will accelerate more sensible construction and targeting of programs of obesity prevention, and may be instrumental in eventual control of this disorder.

Kidney, Urologic and Hematologic Diseases: Kidney and urologic diseases affect more than 13 million Americans and account for over 80,000 deaths each year. Using the most advanced research techniques, scientists have pinpointed the location of the genetic defect in polycystic kidney disease, characterized by the insidious development of kidney cysts and progressive destruction of kidney function. Because of this information, there is now a diagnostic test to detect individuals affected before kidney destruction occurs. Knowing the genetic defect also clears the way for elucidating the nature of the biochemical defect involved and makes possible eventual prevention of one of the major causes of chronic renal disease. Equally important to the families afflicted with this disorder is the fact that the availability of this test allows

physicians to advise family members who do not carry the affected gene.

For the more than 7,000 patients who undergo kidney transplantation each year, substantial progress has recently been made in reducing the associated morbidity and mortality. Further success in kidney transplantation is expected through manipulation at the molecular level of the interaction between the immune system and the transplanted kidney, especially though the use of monoclonal antibodies. These molecules, targeted against the immune cells responsible for transplant rejection, have been shown in clinical trials to achieve a reversal rate as high as 90 percent in ongoing kidney rejection. Additional monoclonal antibodies are now being evaluated in an effort to reduce the adverse side effects of this procedure. A high Institute priority will be to improve the outcome of kidney transplantation in children.

The Institute now has under way, in collaboration with the Health Care Financing Administration, a major multicenter clinical trial to assess the effects of diet therapy on the progression of chronic renal disease. The results of this study are likely to have an important impact on the use of dietary modification in treatment of chronic renal disease.

Urinary tract infections account for much of the renal failure in end-stage renal disease in both adults and children. We are therefore gratified to discover that immunization against the most common offending organism in this condition can be effective. The Institute is also intensifying efforts to follow up on research advances relating to benign prostatic hyperplasia and sexual dysfunction, both important and growing health problems.

Institute-supported scientists have opened a new avenue of therapy for patients with aplastic anemia, a progressive and usually fatal disease typically resulting from an unexplained failure of the bone marrow to produce blood cells. Upon finding that bone marrow failure is not complete or irreversible, but possibly due to an immune response, these investigators tried a new procedure which suppresses the immune system. This procedure restored normal bone marrow function in some of these patients.

This program also has earned the credit for two remarkable advances in molecular genetics. In one, scientists have for the first time altered a specific gene in human cells. This gene, which directs the synthesis of hemoglobin, is the one that is defective in blacks with sickle cell anemia. The second advance involves the cloning of the human gene for erythropoietin, which regulates the production of red blood cells by the bone marrow, and the production of this hormone from these clones. The availability of erythropoietin in commercial quantities will make possible an improved quality of life in patients who are anemic because unable to produce this hormone, including the 70,000 patients in the U.S. who have chronic renal failure.

Conclusion: The accomplishments I have presented were made possible because of a strong commitment to a comprehensive research effort. This effort requires the talent and skill of new investigators. The Institute is making every effort to maintain the momentum of our support of research training and research career

awards. We also recognize the important contribution made to the NIDDK program by our centers of research excellence. In the coming year, we will be supporting 31 centers encompassing research in cystic fibrosis, diabetes and endocrinology, obesity, clinical nutrition, and digestive diseases. We are striving to maintain a balance between the fundamental research which is the promise of the future and the clinical research which makes research findings accessible to us now.

Mr. Chairman, the 1987 budget request for this Institute is $418,971,000. I will be pleased to answer any questions.

Biography of Dr. Pierre Renault

September 21, 1936. San Francisco, California. Married, three children.

Education: B.S., University of California, San Francisco, 1959. M.D., University of California Medical School, San Francisco, 1962.

Professional History: 1962-63, Intern, University of California, San Francisco. 1963-64, Junior Assistant Resident, University of California, San Francisco. 1964-66, U.S. Navy, Lt., Chief of Medicine, Station Hospital N.A.S., Lemoore, California. 1966-69, Resident, University of Chicago. 1969-70, Director, Northside Clinic, State of Illinois Drug Abuse Program. 1969-71, Instructor, University of Chicago. 1969-71, Assistant Director, Psychiatric Consultation Service, University of Chicago Hospitals. 1971-74, Assistant Professor, Department of Psychiatry, University of Chicago. 1970-73, Consultant to State of Illinois Drug Abuse Rehabilitation Program. 1971-73, Acting Director, Psychiatric Consultation Service, University of Chicago Hospitals. 1973-74, Director of Research, State of Illinois Drug Abuse Rehabilitation Program. 1974-76, Clinical Assistant Professor of Psychiatry, Georgetown University, Washington, D.C. 1974-80, Chief, Clinical Behavioral Branch, Division of Research, National Institute on Drug Abuse. 1974-82, Private Practice of Psychiatry, Chevy Chase, Maryland. 1975-1986, Assistant Professor of Psychiatry, The Johns Hopkins University School of Medicine, Baltimore, Maryland. 1980-82, Associate Director for Medical and Scientific Evaluation, National Center for Health Care Technology. 1982-83, Associate Director for Program Planning and Analysis, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health. 1983-present, Deputy Director, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health. 1984-present, Liaison Psychiatrist, Liver Diseases Section, Digestive Diseases Branch, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health. 1984-present, Medical Staff of the Clinical Center, National Institutes of Health.

Professional Organizations: Washington Psychiatric Society, American Psychiatric Association, Distinguished Affiliate of the Division of Psychopharmacology of the American Psychological Association, American Association for the Advancement of Science.

Honors, Awards: PHS Commendation Medal, 1982.

ISLET CELL TRANSPLANTATION

Senator WEICKER. During last year's hearings, you answered a question concerning funding for cell transplantation research in diabetes as follows:

> This research effort is not built into the fiscal year 1986 budget request because it is based on recently emerging scientific opportunities.

I would expect that that kind of situation must arise on a regular basis. How do you normally respond, and have you had much difficulty with OMB in being a flexible manager?

Dr. RENAULT. In the particular case?

Senator WEICKER. In any case that arises of that nature, yes.

Dr. RENAULT. We have not experienced any difficulty here at all. I believe that the status has not changed in the sense that the whole technology of islet transplantation is still very experimental. It is still being conducted on an investigator-initiated basis.

We have followed it very closely. We have tried to function in a coordinated way. We have held several meetings with individuals interested in this technology. Furthermore, the National Diabetes Advisory Board, in conjunction with our staff, is developing a plan to address this technology in the future.

Conceivably within the next few years, we might be able to put together a more comprehensive effort.

REPROGRAMMING

Senator WEICKER. In last year's report, we reminded "the Director of NIH, and the directors of the various Institutes that they retain the responsibility to authorize minor shifts in subaccount budget authority to take advantage of unanticipated research opportunities. The committee expects this authority to be used as appropriate."

Have you been permitted to apply this amount of flexibility in shifting funds for new opportunities?

Dr. RENAULT. Yes; where the case has arisen. This is not large amounts, of course, but we have certainly had that opportunity.

CLINICAL TRIALS

Senator WEICKER. How many clinical trials were funded in 1986?

Dr. RENAULT. I believe the number is five new clinical trials. I am sorry that I don't have a total number, but it is certainly on the order of about 100 that we support.

Senator WEICKER. Of the five new clinical trials, how many will be funded in 1987?

Dr. RENAULT. In 1987, we don't plan to fund any new clinical trials at this time.

Senator WEICKER. How many, in your initial budget request, had you asked to fund?

Dr. RENAULT. Five.

Senator WEICKER. Would you tell me what those five were?

Dr. RENAULT. Yes; I can give you the title and a brief description.

Senator WEICKER. If you could just synopsize each one for me.

Dr. RENAULT. The treatment of short stature with human growth hormone. This would involve using recombinant biosynthetic growth hormone.

Senator WEICKER. Is that the thing that Genentech came out with?

Dr. RENAULT. Yes; there are other commercial sources coming along, but Genentech currently has one.

Senator WEICKER. Just out of curiosity, why would that be the subject of a clinical trial if, indeed, there is an accepted product? I believe the Genentech is FDA approved.

Dr. RENAULT. I am not sure if it is the Genentech product or not.

Senator WEICKER. Why would you then go through another clinical trial on something that is established?

Dr. RENAULT. This would be slightly different. We know that this product is safe and effective in individuals who are deficient in growth hormone, but there are other situations in which children, who are of short stature, but are not deficient in growth hormone, who are not totally deficient in growth hormone, may have a relative deficiency, something along that line.

Senator WEICKER. That is interesting. As a matter of fact, I was talking to Claudia the other day, and we were talking about the Genentech product. I said to Claudia, I wonder if that product can be applied to my Down's child, Sonny, because you know that Down children tend to be on the shorter side. I was asking the very question that you are posing here, whether it has another use for another reason, for somebody being short. That is the thing that you are talking about.

Dr. RENAULT. Exactly. I think that one of the real benefits of having this recombinant product is that it gives us not a limitless, but a huge supply compared to what we had before, where the hormone had to be extracted from human pituitaries.

So it allows us now to expand into other areas, looking for possible uses.

Another trial that we had proposed to fund is one on postoperatively decompressing the stomach and the gastrointestinal tract. After you have had abdominal surgery, there is a state called paralytic ileus, which is almost inevitable, and this can last 7 or 8 days, and even longer in some individuals. It is a major part of the long recovery time after surgery. It is one of the major problems.

There are some ideas about decompressing the stomach and actually feeding individuals while decompressing. The field is very supportive in trying to see if this period of paralytic ileus couldn't be shortened.

We have another trial which would be a cooperative effort to look at kidney transplantation in children with end-stage renal disease. The object here would be really to look at different protocols and try to come up with optimal protocols for children in transplantation.

We also had wanted to do a clinical trial of Hematin therapy for acute porphyria. Hematin actually could be considered an orphan drug. There is considerable evidence that Hematin could be a way of treating acute porphyric attacks but it is a rare disorder, and it would really require a multicenter approach, a coordinated approach to try to get that information.

Another study that has been proposed is a nonsurgical reduction of the stomach capacity for the treatment of morbid obesity. This really involves putting essentially a balloon type of device into the stomach and there is such a device that is approved and is being used. There are several questions around this. I don't question the fact that it is efficacious, but there are a lot of questions about its use, and the mechanism of action, basically.

Senator WEICKER. This sort of falls into the same category of things as Dr. Goldstein's clinical trials to prove that a certain surgery didn't work.

Dr. RENAULT. Yes; we don't want to prejudge.

Senator WEICKER. I didn't realize that these clinical trials went on that basis also. I think that it is obviously a good thing if they do.

Dr. RENAULT. It is very important, especially in costly technologies that impact on patients. We certainly don't want anything that is not effective.

JUVENILE DIABETES

Senator WEICKER. Juvenile diabetes is a disease that starts in children and continues its debilitating effects throughout a somewhat shortened lifespan.

Can you estimate for us what the individual cost might be to a child born with this disease throughout his life time? Please include medical treatment costs, as well as economic loss caused by the debilitating aspects, and shortened lifespan.

Dr. RENAULT. I don't have that figure.

Senator WEICKER. Would you submit that for the record?

Dr. RENAULT. I will.

[The information follows:]

JUVENILE DIABETES

We cannot provide a reliable estimate because there is no accurate data on either the yearly costs incurred by a child with diabetes or on the lifespan of a child born with diabetes. However, we can make some general estimates derived from available data in populationwide surveys. The direct costs of routine medications, monitoring materials, and physician care is probably around $100,000 over the life time of an insulin-dependent diabetic who gets the disease at a young age. It would be reasonable to double the number to include total hospitalization and specialized medical care costs, and then double this amount again to account for the lost productivity and premature mortality due to this chronic and progressively debilitating illness. Therefore, the final economic cost of this type of diabetes is approximately $400,000 per patient life time, with one-half ascribed to direct medical costs and one-half in indirect lost productivity costs. This calculation is based on a number of assumptions that require further research, and the true number probably lies between one-half and two times this value.

However, the total economic impact in the United States of diabetes and its complications was estimated in 1984 to approximately $14 billion annually. This includes $7.4 billion associated with the direct costs of medical and health care services, $4.4 billion associated with the indirect costs due to disability resulting in lost wages and earnings, and $1.9 billion in indirect costs due to premature death resulting in lost wages and earnings. Although only 5 to 10 percent of all people with diabetes have the juvenile-onset form of the disease (IDDM), the economic burden for health care, morbidity, and mortality associated with IDDM clearly exceeds 5 to 10 percent of the total costs associated with all forms of diabetes and its complications. Therefore, the total costs associated with IDDM are more tha $1.4 billion but less than $14 billion per year.

COST OF RESEARCH INTO JUVENILE DIABETES

Senator WEICKER. How many juvenile diabetics are there in this country?

Dr. RENAULT. Approximately 1 million.

Senator WEICKER. How much are we spending each year on research into juvenile diabetes?

Dr. RENAULT. I would have to submit that for the record, as well. We don't have a figure for juvenile diabetes, we put it all together as diabetes.

[The information follows:]

DIABETES AND RELATED RESEARCH
Obligations

	1983 Actual	1984 Actual	1985 Actual	1986 Appropriation	1986 Available After Sequestering	1986 Revised Estimate	1987 Estimate
Public Health Service:							
National Institutes of Health:							
National Institute of Diabetes and Digestive and Kidney Diseases..	$84,500,000	$92,444,000	$103,977,000	$109,500,000	$104,700,000	$103,100,000	$101,100,000
National Cancer Institute.....	634,000	650,000	454,000	600,000	620,000	580,000	560,000
National Heart, Lung and Blood Institute.....	16,720,000	17,121,000	19,135,000	20,500,000	19,600,000	19,300,000	18,700,000
National Institute of Dental Research.....	1,997,000	2,098,000	4,523,000	4,922,000	4,710,000	4,710,000	4,600,000
National Institute of Neurological and Communicative Disorders and Stroke.....	6,639,000	7,430,000	4,314,000	4,719,000	4,516,000	4,412,000	4,365,000
National Institute of Allergy and Infectious Diseases.....	5,408,000	5,452,000	5,692,000	5,886,000	5,633,000	5,605,000	5,345,000

DIABETES AND RELATED RESEARCH (continued)
Obligations

	1983 Actual	1984 Actual	1985 Actual	1986 Appropriation	1986 Available After Sequestering	1986 Revised Estimate	1987 Estimate
Public Health Service:							
National Institutes of Health:							
National Institute of General Medical Sciences.	943,000	849,000	1,056,000	1,100,000	1,100,000	1,100,000	1,100,000
National Institute of Child Health and Human Development.....	8,692,000	10,758,000	11,545,000	11,900,000	11,400,000	11,300,000	11,400,000
National Eye Institute.....	21,054,000	22,696,000	20,850,000	23,200,000	21,600,000	21,500,000	21,300,000
National Institute of Environmental Health Sciences..	132,000	331,000	311,000	315,000	315,000	315,000	320,000
National Institute on Aging.....	2,362,000	1,797,000	2,007,000	2,182,000	2,089,000	2,056,000	2,036,000
Division of Research Resources.....	16,190,000	16,356,000	15,107,000	15,462,000	14,797,000	14,797,000	14,105,000
Total, NIH....	165,271,000	177,982,000	188,971,000	200,286,000	191,080,000	188,775,000	184,931,000

NEW ARTHRITIS INSTITUTE

Senator WEICKER. How is the arthritis portion of your endeavor coming along? What is the impact there on your Institute?

Dr. RENAULT. We have put together a plan, and that plan is progressing. It is a 3-year plan. During the first year, this year, we have planned to essentially create the two separate entities. We expect that by 1988, the two Institutes will be fully independent.

DIABETES CONTROL AND COMPLICATIONS TRIAL

Senator WEICKER. You have informed this committee of your plans to conduct a major diabetes control and complications trial. Would you like to discuss that now? Is this trial going to go forward in the coming fiscal year?

Dr. RENAULT. Very definitely. This has gone through a planning phase, where we had a large input from the community. The community has felt strongly that this study addresses one of the most fundamental issues in treating diabetes. We have gone through a feasibility trial, where on a small scale, a clinical trial was conducted, and this was evaluated by two independent committees, looking at various aspects of the feasibility. This last year, both committees reported very favorably, stating that they felt that the trial was feasible and would likely achieve its desired results.

So we have gone ahead, and we have initiated the full-scale clinical trial at the beginning of this year.

CYSTIC FIBROSIS

Senator WEICKER. Last, before Senator Proxmire's questions, I understand that the underlying genetic defect present in cystic fibrosis has been identified. Would you like to comment on that, and would you tell where exactly that puts us in overcoming this disease?

Dr. RENAULT. Yes; the area of cystic fibrosis has really gone through a tremendous transformation over the last few years. I think that we have gotten, both because of the efforts of our Institute, but also the Cystic Fibrosis Foundation, a lot of really excellent researchers involved in cystic fibrosis, and they have become interested in the defect that causes this disease.

What has occurred in the last year is a marker which is near the gene. It is not the gene itself, but it considerably narrows the effort to actually find the defective gene. I think that it is a very hopeful and very encouraging development. We hope that it is going to accelerate our ability to identify the genetic defect.

Senator WEICKER. Do you have enough funds to pursue research in this area?

Dr. RENAULT. Yes; I believe we do. It is certainly a high-priority area for us. We have a cystic fibrosis center, which is funded and continuing, and we also have investigator-initiated research in this area.

Dr. WYNGAARDEN. There are many Institutes that have programs that

relate to cystic fibrosis. The Diabetes Institute has about $7 million in that field, but the total NIH has $20 or $21 million. At least six different Institutes have work in cystic fibrosis.

Dr. RENAULT. We have also made some changes in our intramural program, and we have asked some of our intramural scientists to direct their attention to cystic fibrosis. Just this year, actually, we have had a presentation from one of our intramural scientists on a test for cystic fibrosis which looks very promising. It looks promising even in its ability to identify carriers of the disease, people who are not affected, but who actually might have offspring with cystic fibrosis.

It is very preliminary, but it is the results of our efforts to give this disease a high priority.

Senator WEICKER. Senator Proxmire.

END-STAGE RENAL DISEASE

Senator PROXMIRE. Dr. Renault, in your prepared statement, you indicate that immunization can be effective in preventing end-stage renal disease resulting from urinary tract infections. Is this procedure in general use as yet and, if not, when will it be?

It sounds very promising, not only from the standpoint of saving money, but far more importantly in saving lives.

Dr. RENAULT. It is not in general use. I believe the procedure you are referring to would be immunization with bacteria that are a common cause of urinary tract infections, E-coli. This is still experimental. I think what is unique about it is, it has worked in animals in this way, it would be a vaginal immunization that conveys protection to the urinary tract. This is quite unique and innovative.

Senator PROXMIRE. Can you give me any notion of when it might be reasonable to expect the vaccine to be available?

Dr. RENAULT. I don't think that it is imminent at all. I think that it would take several years to fully develop this so that it could be used in the general population.

NUTRITION PROGRAM

Senator PROXMIRE. On page 5 of your prepared statement, you say that your intramural and extramural nutrition research programs underpin research throughout your Institute and NIH. Does that mean that you are the lead Institute for basic nutritional research at NIH?

Dr. RENAULT. We certainly regard ourselves as the lead Institute, but nutrition, of course, is something that is in every Institute and is of great concern to the entire NIH. We think that our interest is, as you have indicated, in basic nutritional research, really we see that as an extension of research in metabolism, where substances are metabolized and have effects on the body.

Senator PROXMIRE. I think that proper nutrition has great prospects for improving human health, longevity, and vitality. Recently there was a remarkable exercise study, as you undoubtedly know, at Harvard. They studied 17,000 people over a period of many years, and they found benefits from moderate exercise.

I haven't seen any comprehensive study of that sort involving nutrition. I think such a study would be even more rewarding. We have studied tobacco, which we should, because it is a killer, but nutrition, which seems to me to be perhaps the best preventive measure that we can advance, seems to have been somewhat neglected.

Dr. RENAULT. Nutrition is a complicated thing to study.

Senator PROXMIRE. There are many economic interests involved, including interests in my own State. We are a dairy State, and we don't want anybody to say that if you drink a lot of milk it is going to affect your heart. People say that, and, of course, they are wrong when they do. [General laughter.]

We would like to have as much objective and expert understanding of nutrition as we can get.

Dr. RENAULT. There are several things happening in nutrition research. There is a broader awareness of the importance of nutrition. Clearly, in the Heart Institute and the Cancer Institute there are major initiatives in prevention, which involve nutrition.

In our Institute, I think that we have benefited a great deal from modern molecular biology in nutrition so that we are really focusing down on very specific aspects of nutrition.

Senator PROXMIRE. How much do you plan to spend on nutrition research in 1986 and 1987?

Dr. RENAULT. For our Institute, our estimate is $35 million. For the NIH as a whole, it is $202,700,000 in 1987.

Senator PROXMIRE. How does that compare with 1986?

Dr. RENAULT. Our estimate is, for our Institute, that it would be $36,650,000, so 1987 would be about $1 million less.

Senator PROXMIRE. So you are cutting nutrition research support.

Dr. RENAULT. For the NIH as a whole, it would be $206,937,000.

Senator PROXMIRE. That is a reduction also?

Dr. RENAULT. In 1987, it would go down to $202,700,000. So it is roughly $4 million.

Senator PROXMIRE. Even in nominal terms, it is a cut, and in real terms, it is an even more substantial reduction.

Dr. WYNGAARDEN. It is proportional to the whole budget.

Senator PROXMIRE. Nutrition research is the kind of activity that can probably do more good than almost anything. It doesn't have the urgency or the human appeal, perhaps, of some of the other areas where you wisely spend money, but it is something that I think we can pursue with great profit for the health of the country.

Does the individual who heads up your nutrition program have a degree in nutritional science?

Dr. RENAULT. He is an M.D. Ph.D., and his Ph.D. is in biochemistry.

Senator PROXMIRE. That is encouraging.

Dr. RENAULT. I think that he is very well qualified. He is exceptionally well qualified.

Dr. WYNGAARDEN. We have a new appointee there who is very well qualified.

Dr. RENAULT. That is true, our Division Director.

TRAINING IN NUTRITION

Senator PROXMIRE. I understand that the subject of nutrition tends to be given scant attention in the curricula of most medical schools. Does that concern you and, if so, is your Institute looking into ways of dealing with that problem?

Dr. RENAULT. We certainly have heard that from the field. We recently got a letter on that subject. We would like to see more in medical school curricula to educate physicians about the importance of nutrition and about the substantive aspects of nutrition, how to advise patients, and what have you.

I think, though, that the position that we have taken is that our primary role is in nutritional research, and we have not had any initiative in changing medical school curricula, other than indirectly, by enhancing nutritional research which will certainly interest medical students.

Senator PROXMIRE. You will be in a position to make at least some useful observations and recommendations, which would be, it seems to me, quite influential.

Dr. RENAULT. Clearly.

Senator PROXMIRE. I know that you can't tell medical schools what to do, but you can be helpful.

Dr. RENAULT. If we support nutritional research, and students in other faculties see the excellence of that field as it develops, I think that it will have a very positive effect on the curricula.

NUTRITION COORDINATING COMMITTEE

Senator PROXMIRE. One more question: How is your nutrition research program coordinated with the nutrition research being supported by the Cancer and Heart Institutes?

Dr. RENAULT. The NIH has a nutrition coordinating committee, and we participate on that committee as do virtually all of the other Institutes.

Dr. WYNGAARDEN. There are representatives of all of the Institutes with nutrition programs on the NIH nutrition coordinating committee, and it is a very active committee. It not only coordinates the work that is going on, but it plays a major role in catalyzing certain conferences. For example, the recent one on unsaturated fatty acids, and similar products, and their role. The correlation of the intake of these substances with lower rates of vascular disease, for example, that is the sort of thing that our nutrition coordinating committee routinely does.

Senator PROXMIRE. How many such conferences do you intend to have in 1987?

Dr. WYNGAARDEN. In 1987, the committee will cosponsor approximately two conferences.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Thank you very much, Dr. Renault. There will be further questions for response to the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

ENDOCRINE RESEARCH

Question: There is a growing awareness of the importance of endocrine research. What are you doing to expand work in this area?

Answer: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) supports basic and clinical research on the endocrine glands, their hormones and diseases associated with their dysfunction. The Institute maintains a strong basic and clinical research program in endocrinology utilizing innovative techniques in molecular biology, immunology, genetics and cell culture. In addition, a large proportion of the Institute's other research programs involve research in endocrinology. The majority of the Institute's resources are devoted to investigator-initiated research project grants through which investigators in the field pursue the most promising research opportunities in endocrinology. Consequently, the Institute's plans related to endocrine research emphasize the continued expansion of investigator-initiated studies oriented toward fundamental research in endocrinology. In addition, the Institute continues to stimulate and support multidisciplinary efforts to further elucidate endocrine processes and their regulation, as well as clinical studies aimed at transferring advances in fundamental knowledge into clinical practice. Both clinical and basic efforts continue to be essential for the further development of improved strategies for the diagnosis, treatment, cure and ultimate prevention of endocrine disorders.

Question: Would you support fitting the "E" for endocrinology in the Institute's name?

Answer. Subsequent to the President's proposal to establish a National Institute of Arthritis and Musculoskeletal and Skin Diseases, the NIH Legal Advisor was consulted for his opinion on NIH authority to establish a National Institute of Diabetes, Endocrinology, and Digestive and Kidney Diseases. The Legal Advisor reviewed the arguments and concluded that the establishment of an institute with the word endocrinology in its name would directly conflict with the provisions of P.L. 99-158 that establishes the National Institute of Diabetes and Digestive and Kidney Diseases. The NIDDK has been established by statute and is given certain authorities by statute. A National Institute of Diabetes, Endocrinology, and Digestive and Kidney Diseases would not have those same statutory authorities.

COST OF GALLBLADDER SURGERY VS. NEW NONSURGICAL TREATMENT

Question. I understand that a new nonsurgical treatment for gallstones is a distinct possibility. How close is this treatment to clinical trials, and how much will the trial cost?

Answer. A study on this treatment is currently underway at the Mayo Clinic under the leadership of Dr. John Thistle.

Dr. Thistle is studying questions of treatment toxicity, efficacy, and dose-response. Initial observations from this study have been exciting. Further, several investigators have submitted an Investigative New Drug Application to the FDA to use and evaluate this treatment. The need for a clinical trial will be considered subsequent to the outcome of these studies. The patient population that is involved in the current studies would be appropriate for subsequent gallstone prevention studies.

Question. Can you tell us how much we are spending on gallbladder surgery each year?

Answer. Medicare data for Fiscal Year 1984 shows a range of costs for cholecystecomy, with or without common bile duct exploration, from $4,657 to $9,309, with the largest group (patients over age 69 and without bile duct exploration) costing $7,015. According to the National Center for Health Statistics, hospitalization time ranged from 8.7 to 14.5 days. Extrapolating these costs to the general population, in which 500,000 cholecystectomies are done each year, the minimum cost would be $2.3 billion dollars.

Question. How much are you budgeting for further research into this nonsurgical approach, and is it enough?

Answer. The Institute will continue to support the research of Dr. Thistle on the nonsurgical treatment of gallstones. These studies cost $85,301 in Fiscal Year 1985 and are expected to continue at about that cost in Fiscal Year 1986. The support of studies on the nonsurgical treatment of gallstone disease has a long history in this Institute, with this current work fostering newer treatment modalities. Future directions of gallstone research will range from basic studies of gallstone formation, costing an estimated $2.5 million per year, to a planned initiative on gallstone prevention, which is estimated to cost $2 million over the next four years. A workshop on gallstone prevention is scheduled for summer 1986. This amount is sufficient to maintain progress in this area. Additional research opportunities include studies on: the frequency and nature of recurrence of gallstones following treatment, the impact on the patient of repeated treatment and the long-term effects of treatment, the possibility of removal of stones in the ducts, and endoscopic alternatives to percutaneous catheterization for the treatment.

JUVENILE DIABETES - RESEARCH COST VS. ECONOMIC COST

Question. Juvenile diabetes is a disease that starts in children and continues its debilitating effects throughout a somewhat shortened life span. Can you estimate for us what the individual cost might be to a child born with this disease throughout his life time? Please include medical treatment costs, as well as economic loss caused by the debilitating aspects and shortened life span.

Answer. We cannot provide a reliable estimate because there is no accurate data on either the yearly costs incurred by a child with diabetes or on the life span of a child born with diabetes. However, we can make some general estimates derived from available data in population-wide surveys. The direct costs of routine

medications, monitoring materials and physician care is probably around $100,000 over the lifetime of an insulin dependent diabetic who gets the disease at a young age. It would be reasonable to double the number to include total hospitalization and specialized medical care costs, and then double this amount again to account for the lost productivity and premature mortality due to this chronic and progressively debilitating illness. Therefore, the final economic cost of this type of diabetes is approximately $400,000 per patient lifetime, with half ascribed to direct medical costs and half in indirect lost productivity costs. This calculation is based on a number of assumptions that require further research, and the true number probably lies between one half and two times this value.

However, the total economic impact in the U.S. of diabetes and its complications was estimated in 1984 to approximately $14 billion annually. This includes $7.4 billion associated with the direct costs of medical and health care services, $4.4 billion associated with the indirect costs due to disability resulting in lost wages and earnings, and $1.9 billion in indirect costs due to premature death resulting in lost wages and earnings. Although only 5-10 percent of all people with diabetes have the juvenile-onset form of the disease (IDDM), the economic burden for health care, morbidity, and mortality associated with IDDM clearly exceeds 5-10 percent of the total costs associated with all forms of diabetes and its complications. Therefore, the total costs associated with IDDM are more than $1.4 billion but less than $14 billion per year.

Question. How many juvenile diabetics are there in this country?

Answer. Only limited data are available concerning the prevalence of juvenile diabetes (IDDM) in the U.S. In the school age population, about 1 child in 600 has IDDM. This corresponds to approximately 120,000 children with IDDM in the U.S. If this rate is simply extrapolated to the entire U.S. population, one would estimate that there are approximately 600,000 people with IDDM in this country. However, this total population estimate would not account for either the onset of IDDM in adults or for the increased mortality associated with IDDM.

Question. How much are we spending each year on research into juvenile diabetes?

Answer. During FY 1985, NIADDK obligated $104.0 million on research and research training related to diabetes mellitus and its complications. In addition, various other NIH institutes provided $85.5 million for further studies related primarily to the complications of diabetes. Therefore, NIH as a whole provided a total of $189.5 million for research and research training in this area. Although the majority of these studies are related at least in part to juvenile diabetes and its complications, a precise estimate of the associated costs is not available.

CELL TRANSPLANTATION

Question. Last year there was a great deal of excitement generated by the possibility of effective islet cell trans-

plantation. Can you bring us up to date on the research in this area?

Answer. During the past year, there has been very significant progress in research related to transplantation of insulin-producing pancreatic islet cells. These advances have reached the point that centers in St. Louis, Miami, and Minneapolis have now initiated clinical studies involving islet transplants in patients with advanced diabetes who require immunosuppression for maintenance of kidney grafts. These initial studies have clearly demonstrated partial graft function in the majority of islet transplant recipients. Although none of the recipients have yet become totally insulin-dependent, two of the grafts are still functioning at seven months post-transplant. In addition, various technical refinements have been made in the procedures for isolation of human islet cells from the whole pancreas which greatly improve the purity of the transplant preparation. This purified islet cell preparation has also been used very recently in experimental animals to assess the feasibility of transplanting islet cells directly into the liver. At this time, clinical studies are being initiated to assess this site of implantation in the human. Additional clinical and preclinical studies involving differentiated and undifferentiated islet cell transplants are also underway in Dallas, Denver, New York, Philadelphia, and at various other research centers throughout the United States. These studies will involve efforts to further improve the quality and quantity of islet tissue for transplantation, to define the effects of immunosuppression on islet engraftment and function, and to facilitate procurement and preservation of both the pancreas and isolated islets.

Question. Please compare the cost of this promising research to the cost of diabetes to our society.

Answer. During Fiscal Year 1985, NIH support for research related to pancreas transplantation and the development of related technologies was approximately $8 million. This represents approximately .0006 percent of the total estimated economic burden of diabetes and its complications in the United States.

DIABETES TRIAL

Question. You have informed this Committee of your plans to conduct a major diabetes control and complications trial. What will this trial accomplish?

Answer. The DCCT will address some of the most important clinical questions in diabetes today, including (a) whether the derangements of glycemic control which characterize the diabetic state are associated with development of the life threatening and disabling complications of this disease, and (b) whether it is possible to intervene in this process so as to prevent these complications. The DCCT will determine the most effective form of therapy for persons with insulin-dependent diabetes, and these results will direct the future course of treatment of all persons with insulin-dependent diabetes.

Question. What is the status of this trial, and are you requesting enough funding to conduct the trial as expeditiously as possible?

Answer. The trial was planned to be conducted in four sequential phases. The first two of these phases were directed toward determining the feasibility of conducting the long-term, full-scale trial needed to answer the study questions. The results of the feasibility study were reviewed by two groups of non-governmental experts who were independent of any involvement in the trial. Both groups found that by all essential criteria, feasibility had been demonstrated and recommended that the trial proceed with the full-scale study. In October 1985, the initiation of the full-scale study was announced. Follow-up of the 278 subjects who participated in the feasibility will continue until completion of the study. Recruitment of the 1,200 additional subjects needed for the full-scale trial is ongoing and is expected to be completed by mid-1988. Additional clinical centers are needed to meet these recruitment goals. Selection of these new centers will be completed by mid-May, and it is anticipated that they will be ready to commence recruitment by September 1986. Follow-up of all subjects is expected to be completed in 1993. Adequate funding has been requested to complete the study within the stated timeframe.

Question. If the results are positive, what magnitude of savings are we to expect?

Answer. The amount of improvement in health status and quality of life that the volunteers participating in the Diabetes Control and Complications Trial might derive from adhering to the intensive treatment regimen is unknown at this time. One could assume, however, that volunteers in the intensively treated group might experience complications at a rate which is 25 percent less than in the control group. The total cost of diabetes and its complications to the U.S. economy has been estimated by the National Diabetes Data Group to be approximately $14 billion in 1984. The volunteers in the DCCT all have insulin-dependent diabetes mellitus (IDDM) and patients with IDDM account for approximately 5-10 percent of all people with diabetes; therefore, one could ascribe 5-10 percent of the costs of diabetes to IDDM or up to $1.4 billion per year. Taking 25 percent of $1.4 billion yields $350 million for a very conservative estimate of the potential annual savings to the U.S. economy of intensive therapy for IDDM in terms of medical care, disability and lost productivity. This is probably a gross underestimate of the true costs of IDDM, because IDDM accounts for a disproportionately large share of the morbidity and mortality associated with diabetes.

Question. How does this compare to the costs of diabetes and to the total cost of the trial?

Answer. The annual total costs of diabetes to the U.S. economy was estimated to be $14 billion in 1984 by the National Diabetes Data Group. While the results of the DCCT will be directly applicable to the treatment of insulin-dependent diabetes mellitus (IDDM), it is anticipated that demonstration of any benefit of intensive diabetes management by the DCCT may also be applied to the treatment of noninsulin-dependent diabetes mellitus (NIDDM). If the benefit accrues to this much larger group of

57-852 O—86——21

people with diabetes, the savings to the U.S. economy could amount to several billion dollars each year. The total cost of the full 10 year clinical trial has been estimated to be $153 million or an average cost of $15 million per year or roughly 0.1 percent of the annual economic burden of diabetes and its complications in the U.S.

CREUTZFELDT-JAKOB DISEASE

Question: What is the status of human growth hormone treatment and Creutzfeldt-Jakob disease?

Answer: NIDDK supports the collection and distribution of pituitaries and hormones for research purposes. Until 1985, pituitary-derived human growth hormone (hGH) was distributed for clinical research that included people with a deficiency of growth hormone (leading to short stature) or with hypoglycemia (low blood sugar).

In early 1985, PHS officials were notified that three people in the United States who received hGH from the National Hormone and Pituitary Program (NHPP), which is supported under contract by the Institute, died from Creutzfeldt-Jakob disease (CJD). This is a rare brain disease caused by an infectious agent that has an extremely long incubation period. Because of the rarity of CJD, PHS officials believe it is likely that one or more pituitaries used in the process to extract hGH came from a person or persons with CJD.

On May 29, 1985, the Acting Assistant Secretary for Health established the Interagency Coordinating Committee on Human Growth Hormone and Creutzfeldt-Jakob Disease to facilitate scientific review of the issue. The Committee is chaired by the Acting Director, NIDDK, and includes representation from the NIH (NIDDK, NICHD, NINCDS, Clinical Center), the FDA, and the CDC.

Distribution of the hGH was halted and arrangements were made for people with life threatening hypoglycemia to receive the recombinant hGH product made by Genentech, Inc. The recombinant product was approved for human use by the FDA on October 18.

The status of actions taken by the Committee regarding this issue follows.

Epidemiology: No additional cases of CJD have been reported in recipients of hGH in the United States. One confirmed case in Great Britain was reported previously. The Committee is investigating reports of a possible case in Brazil.

Efforts are underway to identify all recipients of hGH distributed by the NHPP. Data abstraction forms have been sent to medical centers where patients were treated with hGH. The information will be used (1) to match patient names against the National Death Index to determine any unreported cases of CJD; (2) to provide an information base for the long-term epidemiology study; (3) to contact patients if any treatment, prevention, or palliative therapy for CJD becomes available. A long-term epidemiology study will be conducted to ascertain the health status of each patient.

The contract for this study will soon be awarded. Funding is provided by NIDDK and NICHD.

Infectivity of Lots of hGH: Each dose of hGH was obtained from a lot of hGH derived from an average of 16,000 pituitaries. No single lot was shared by the three patients who died. The question of infectivity is to determine which lots of hGH were contaminated to provide patients with an estimate of risk for CJD. Because no generally accepted laboratory test exists to determine contamination with the agent responsible for CJD, animals must be inoculated with doses from lots of hGH to see if they develop the disease. In May 1985, animal studies were begun using 26 of 33 lots of hGH received by the three patients who died and samples of 53 other lots given to patients, but not associated with CJD. The animals will be followed for five years; at this time, none show signs of CJD.

Processing of Pituitaries: The FDA and the NIH cosponsored a workshop on October 21 and 22 to discuss appropriate methods to test whether a product contains the CJD agent, and in the case of negative results, the level of assurance that the product is not infectious for humans. The attendees included expert virologists, representatives of drug companies, the contractor responsible for processing pituitaries for the Hormone Distribution Program of the Institute, and officials from the NIH and the FDA.

The workshop participants outlined protocols to test the efficacy of purification methods to produce growth hormone preparations free from contamination.

The purpose of testing the production process is to provide past recipients of hGH with an estimate of safety concerning the preparations they received and provide an estimate of the possibility of producing a pituitary-derived product safe for human use. Since many cases of CJD are unrecognized at death and carriers of the agent may be asymptomatic, merely excluding pituitaries from known cases of CJD is not adequate to ensure lack of contamination of human pituitary preparations. It must also be shown that the method of production of pituitary hormones is sufficient to exclude the CJD agent. It is important to note that at the time the Hormone Distribution Program was established, it was not known that CJD was caused by an infectious agent. Even after this became known, it was some time before scientists realized that the CJD agent became extremely resistant to methods of decontamination.

The experiments formulated during the FDA/NIH workshop are necessary for developing an accurate and reliable method of process validation, that is, a method of determining whether various techniques of treating pituitary hGH are effective in eliminating or inactivating slow virus agents. Process validation, however, is only one part of testing a drug for use in humans. Other measures are needed to ensure that a therapeutic product derived from human tissues is safe. One of these measures is safety testing which, up to this time, has always been necessary before FDA approval of a drug for clinical use. However, safety tests of hGH in primates would require observation periods of at least 5 years, which could actually exceed the shelf life of the production lot under test, thereby making safety testing unfeasible.

NIDDK officials will make a final determination on proceeding with the validation studies after consultation with the Endocrinology Research Program Advisory Committee at their ad hoc meeting in June and further discussion with the Interagency Coordinating Committee. Preliminary work to prepare tissue that would be needed for the studies is under way in intramural NIH laboratories.

KIDNEY DISEASE

Question: I note that End-Stage Renal Disease is costing the Federal Government over $2.8 billion annually, and I understand that you are establishing a clinical trial to test the efficacy of dietary modifications in the treatment of renal disease. How much will this trial cost, and if its findings are positive, how much of the $2.8 billion would be saved each year using this treatment?

Answer: The costs to NIH for the trial on efficacy of dietary modifications in the treatment of renal disease are estimated at $2.6 million annually for 1985 and 1986; $13 million annually for 1987 through 1990; and $750,000 for 1991. The estimated cost savings are that for each year that dialysis is delayed, the net savings would be at least $17,000/patient. Since the number of new patients per year has been expanding at a rate of 10 percent per year, and the number entering in 1984 was nearly 8,000, the net savings for 1985 would have been $136 million. Thus the total cost of the seven year study is less than one-half of the net savings of just a one year delay. This figure takes into account the most generous estimate of the total cost of providing dietary advice/control and necessary health care. If these are not provided, the net savings would be $192 million per year. Since it is quite likely that a positive result would result in substantially more than a one year delay, the cost savings could potentially be significantly higher. More important is the potential for halting the spiraling costs of this program.

KIDNEY CENTERS

Question: We have been receiving some inquiries concerning the establishment of research centers in the area of kidney diseases. Would kidney research centers intensify the research efforts in kidney disease, and what are your plans to establish such centers?

Answer: The science base that has been achieved in kidney and urinary tract diseases is now at a level that offers emerging research opportunities. Each of the areas in which centers are proposed (hypertension, diabetes, immunology, nutrition, obstructive and hereditary diseases) offer compelling research challenges and opportunities which can be pursued effectively through the centers program.

The NIDDK has issued a Request for Applications (RFA) for kidney and urological research centers. Some 23 research groups throughout the U.S. have demonstrated a strong interest in applying for centers grants by submitting Letters of Intent in response to the recently issued RFA. However, the President's budget does not include funds for new centers.

DIGESTIVE DISEASE CENTERS

Question. Have you developed your plans for research centers on digestive diseases?

Answer. Planning for digestive disease centers continues and is based on the recommendation of the National Digestive Diseases Advisory Board (NDDAB) for a program of 14 centers. Six new digestive disease centers were added to the two existing centers in Fiscal Year 1984. In Fiscal Year 1985, four additional centers were established to bring the total number of digestive disease centers to twelve. These centers are located throughout the United States and focus on basic research and disorders related to gastrointestinal motility, structure and function relationships, secretion and absorption processes, and hormones; and to diarrheal, inflammatory bowel, and liver diseases. Current projections for the digestive disease centers program of the Institute recognizes the intent of NDDAB to achieve two additional centers and to expand some of the existing centers to accomplish a broader role as comprehensive centers.

Question. What kind of research will these centers focus on?

Answer. The 12 existing digestive disease centers focus on liver diseases, inflammatory bowel disease, diarrheal diseases, and basic digestive diseases research in the areas of gastrointestinal motility, structure and function relationships, secretion and absorption processes, and hormones. The present portfolio of digestive disease center grants does not include research activity which is focused in two other areas designated by the NDDAB: pancreatic disorders and pediatric gastroenterology research.

HORMONE RESEARCH

Question. I have read that endocrinology, the study of hormones, is now showing a great deal of promise. You have told the Committee that in the past five years alone over 50 hormones have been described that regulate cell growth and affect the immune and nervous systems. What is the status of research in this area, and can you report any promising breakthroughs?

Answer. There are a number of very exciting recent research advances in endocrinology with important and far reaching implications for clinical medicine. For example, concepts developed by endocrinologists studying hormones and their receptors are being rapidly integrated into the field of oncology as the molecular mechanisms by which cells undergo malignant transformation are elucidated. Growth factors, receptors, and transducers have been increasingly implicated in certain forms of cellular transformation and malignancy. Some products coded by genes capable of tumorigenic transformation of normal cells ("oncogenes") have been shown to be almost exact duplications of hormones such as platelet derived growth factor. Other oncogenes code for slightly modified forms of hormone receptors such as a mutated form of the epidermal growth factor receptor which results in uncontrolled cell growth. The proteins coded by yet another family of oncogenes are similar to the regulatory subunit of the enzyme adenylate cyclase, which is the "second messenger" or transducer through which a number of

hormones act. These discoveries integrating endocrinology and oncology have not yet been translated into the clinical treatment of cancer, but there is potential for clinical applications of this research. Development of antibodies to oncogene products such as tumor growth factors may allow specific removal or inactivation of these products. Hormone-like factors inhibiting tumor growth have also been discovered, and when the mechanism of action is determined, analogs of these factors may be developed to selectively impede tumor growth. This detailed knowledge of the pathways by which cells control their growth may allow development of new and specific drugs to slow or halt tumor growth.

Recently, a number of local growth factors or cytokines have been identified which may play a role in the regulation of bone metabolism. Some of these factors are produced by normal cells and may regulate the normal processes of bone metabolism. Others are produced by human or animal tumors and may mediate the pathological resorption and increased serum calcium levels associated with cancer. NIDDK plans to stimulate research on the effects of these newly discovered cytokines on bone metabolism and the identification of other potential bone active agents. As the mechanism by which these factors regulate bone metabolism becomes understood, specific analogs of these factors may be developed with desirable therapeutic properties, such as inhibition of bone resorption or stimulation of bone formation, useful in therapy of diseases such as osteoporosis or tumor associated hyperglycemia.

A large number of peptide hormones which were originally discovered in the hypothalamus or gastrointestinal tract have recently been identified throughout the central nervous system and shown to be actually secreted from neurons. After the isolation of corticotropin releasing factor (CRF) in 1981, researchers demonstrated that this peptide appears to control both the neural as well as the endocrine responses to stress. CRF has been detected in nerve terminals throughout the central nervous system in a selective distribution, and recently scientists reported a decrease in CRF concentration in certain brain regions in patients with Alzheimer's disease. If this finding is confirmed, its role in producing the symptoms of Alzheimer's disease must be clarified. Similarly central nervous system levels of the hormone somatostatin have been reported to be abnormal in brain tissue from patients with Alzheimer's disease and the significance of this finding is being pursued. Brain levels of a number of neurohormones are now being determined in specific disease states. Many pharmaceutical agents currently used in the treatment of neurologic disorders are analogs of the traditional neurotransmitters. As altered levels of the newly recognized brain hormones are correlated with specific diseases, new drugs which are structurally related to these hormones are likely to be developed.

One example of a newly discovered neuropeptide which is already being actively studied in clinical trials is growth hormone releasing factor (GRF). In many of the approximately 2,000 children in this country who have growth failures due to growth hormone deficiency, the defect lies in the failure of the hypothalamus to produce the peptide GRF which stimulates the pituitary to produce and release growth hormone. Children with growth hormone deficiency have now been treated with GRF for periods of up to

two years, and in many of these children growth rates are comparable to those seen with growth hormone treatment. Since GRF is a smaller peptide than growth hormone, therapy with GRF may prove to be cheaper and easier to administer than growth hormone therapy.

The actions of a number of other hormones newly isolated from a variety of tissues are now being investigated. Immunologists are applying techniques of endocrinology to the study of hormone-like factors, or lymphokines, which have been shown to have major effects on the function of cells in the immune system. New hormones with powerful effects on the regulation of blood pressure and renal function have been isolated from heart tissue. In an exciting development in 1983, investigators were able to predict the existence of a previously unknown hormone, calcitonin gene related peptide, based on an analysis on the cloned gene for the known hormone calcitonin. This year scientists raised antibodies to the hormone and demonstrated that it actually circulates in human blood. Further, it has been shown to have potent effects on blood vessels and blood pressure.

Thus, identification of new hormones and characterization of their often effects on a wide ranging number of systems is an area in which progress has been rapid in the past few years. Understanding of the actions of these new hormones will have a profound influence on a number of areas including neurobiology, immunology, gastroenterology, cardiology, and oncology. In turn, clarification of the mechanisms of action of these newly discovered hormones will provide valuable insights into the molecular and cellular aspects of endocrinology.

SEPARATION OF THE ARTHRITIS AND DIABETES INSTITUTES

Question: I understand that the new arthritis institute was created from the Arthritis Division of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases.

Has this division of arthritis from your Institute caused any loss in staffing and budget authority that was not allocated to the Arthritis Division in the old NIADDK?

Answer: No, the separation of the two Institutes has not resulted in any loss of staffing or budget authority for either organization. In Fiscal Year 1986, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) has been allocated a budget corresponding to that appropriated by Congress to the Division of Arthritis, Musculoskeletal and Skin Diseases of the parent Institute, as well as that of arthritis-related portions of that Institute's Division of Intramural Research. For the present, the NIAMS has the staffing resources of the Division and the relevant intramural laboratories of the parent Institute and shares with the NIDDK the services of existing central staff offices.

Question: What impact has the creation of the new Institute had on the research priorities within and between the areas of diabetes, and digestive and kidney diseases?

The NIDDK will continue to support a balanced, high quality research program to combat these diseases. The balance among these

programs is largely determined by the scientific merit of the research proposals developed by the biomedical research communities for diabetes and digestive and kidney diseases. Priorities within each of these areas change as scientific opportunities and needs change. The annual NIDDK planning process enables the Institute to identify these emerging needs and priorities with the assistance of our Advisory Boards and National Advisory Council, as well as the participation of the broader scientific community. Using the findings and recommendations of our planning process, we adapt the Institute's approach and priorities to take advantage of new knowledge and to respond to public health needs.

DIGESTIVE DISEASES - DATA SYSTEM

Question. Digestive diseases have been estimated to cost about $35 billion a year. I understand that you are developing a data system for digestive diseases. Can you tell us when this system will be on line?

Answer. The NDDAB has estimated the annual cost of digestive diseases in the United States to be at least $50 billion. Congress, as part of a response to the burden of digestive diseases, instructed this Institute to establish a data system for the collection, storage, analysis, retrieval, and dissemination of digestive diseases information, and where possible, to include population-based data for risk assessment (P.L. 99-158). The data system is now functional for the collection and management of information on liver transplant patients. A contract to this end has been awarded by this Institute to the University of Pittsburgh. In the future, the Institute intends to work in collaboration with the National Center for Health Statistics and with digestive disease centers to address specific epidemiological questions and issues on digestive and nutritional disorders, such as peptic ulcer, gallstones, inflammatory bowel disease, chronic liver disease, and obesity.

IMPACT OF BUDGET REDUCTIONS

Question. The President's budget proposal for FY 1987 reduces your budget by $33,700,000 under FY 1986 appropriated levels. Gramm-Rudman-Hollings, if triggered, could reduce your budget even further maybe by as much as 20 percent.

I have known this would reduce the number of grants, possibly the size of grants, centers, training, etc., etc.

Can you give us some idea of the impact of these reductions on the kinds of research that would be stopped or lost?

and,

What impact might this have on the health of our citizens five and ten years down the road?

Can you discuss your contingency plans if these massive budget cuts should come to pass?

Answer. At this time, NIH has not developed a specific contingency plan for further sequestrations below the amounts currently requested in the FY 1987 President's budget. However, if NIH were to sustain further cuts in the range of 20 percent, it is safe to assume that all programs would be affected to some degree. As part of a careful review of various options, serious consideration would also have to be given to eliminating certain research activities.

With regard to the impact of further funding reductions on the health of our citizens, it is impossible to project or quantify precisely the consequence of differing research funding levels on the Nation's health in future years. Nevertheless, reductions in the order of 20 percent could not be absorbed without significantly reducing the level of biomedical research supported by the NIH and it is this investment which impacts directly on the future availability and efficacy of new health diagnoses, preventions, and treatments.

Question. If the automatic provisions of Gramm-Rudman-Hollings are triggered in FY 1987, your Institute may well have its budget reduced by 20-25 percent.

Have you prepared a contingency plan in the event Gramm-Rudman-Hollings becomes reality?

If so, please send a copy of your plans to this Committee.

If cuts of this magnitude become reality, how will they be distributed?

1. Intramural vs. Extramural programs;
2. Peer review system:
   Would the number of site visits be reduced?
   Would travel to NIH to study section meetings be affected?

3. Would NIH employees have to be furloughed?

4. What major programs would have to be cut back?

Please list the research programs of the highest priority that should not be cut and why.

Answer. At this time, the NIH has not developed a specific sequestration plan for reductions below the amounts requested in the FY 1987 President's budget. In compliance with the provisions of the Gramm-Rudman-Hollings Act, the President's budget was developed within overall deficit targets which would preclude the need for any sequestrations in FY 1987.

However, if NIH were to sustain further cuts in the 20-25 percent range, all programs would be affected to some degree and serious consideration would have to be given to eliminating certain programs. A careful review of all programs would need to be conducted before such decisions would be made.

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

STATEMENT OF DR. LAWRENCE SHULMAN, ACTING DIRECTOR
ACCOMPANIED BY EARL LAURENCE, EXECUTIVE OFFICER

PREPARED STATEMENT

Dr. WYNGAARDEN. Arthritis is now an independent budget, and I would like to introduce Dr. Shulman, who is the Acting Director.

Senator WEICKER. It is a pleasure to have Dr. Shulman with us, and we look forward to many opportunities of talking with you. This being the first, you don't have any other colleagues as standby here, so why don't you go right ahead. Your statement in its entirety will be placed in the record, and please proceed in any way you care.

[The statement follows:]

STATEMENT OF DR. LAWRENCE SHULMAN

As the Acting Director of this new Institute, I am honored to be the first to present to you the programs and accomplishments of both our extramural and intramural scientists and grantees. These diseases - arthritis and musculoskeletal and skin diseases - are numerous and diverse. They afflict millions of Americans, young and old, causing pain, deformity, disability, and death; and in the aggregate, they impose a staggering economic burden upon us all.

Until recently, with notable exceptions, little was known about the causes of these diseases. With the advent of modern biomedical research technology and a new cadre of committed investigators, this outlook has changed rapidly. Provocative advances in all aspects of disease have created opportunities for research that may lead to discovery of the cause and cure for many of these diseases. I am pleased to be able to share with you some of these promising leads and innovative therapeutic achievements emerging from this program.

Rheumatoid Arthritis: The Institute is coordinating a comprehensive research strategy to capitalize on the latest findings relating to rheumatoid arthritis (RA), the major crippling disorder among the rheumatic diseases. Investigators are seeking to identify the infectious agent or agents responsible for initiating the disease process. One such candidate, a parvovirus called RA-1, has been provisionally linked with human RA. A major study searching for infectious agents in early arthritis is planned. Researchers are refining our understanding of the genetic predisposition to developing RA; this genetic makeup underlies the abnormal immune response to an infection that leads to destruction of joints in RA. Other recent research findings point to a role for the nervous system, specifically substance P, in promoting joint inflammation.

New methods of therapeutic approaches for treating RA have become more numerous and effective. Methotrexate, previously used to treat cancer and psoriasis, seems particularly promising. For the future, advanced techniques of biotechnology are being applied to restore normal immune function, and to block inflammation and tissue damage in RA. Identification of a specific causative agent for RA will provide the opportunity for development of a vaccine or other preventive approach.

Osteoarthritis: More than 16 million Americans have osteoarthritis, the most widespread form of arthritis. It primarily affects the cartilage of the joint, causing it to fray, wear, ulcerate, and, in extreme cases, to disappear, leaving a bone-on-bone joint. An encouraging finding of recent research is that osteoarthritis is not necessarily caused by aging. Detailed studies have revealed major biochemical differences between aging cartilage and osteoarthritic cartilage. Recent epidemiologic studies have shown that in older populations the prevalence of osteoarthritis does not increase with age. Research has also refuted the simplistic concept that osteoarthritis results necessarily from wear and tear of the joints. Recent research indicates that long-distance runners over 50 years of age have no more osteoarthritis than "mature" nonrunners.

Opportunities have now become available for increased productive research on fundamental mechanisms of osteoarthritis. Much is being learned in the field of articular cartilage biochemistry. Substances have been identified that regulate the abnormal behavior of cartilage cells in osteoarthritis. Improved understanding of interrelationships between biochemical and biomechanical changes in causing osteoarthritis present important opportunities to block the disease process at any one of a number of steps. Efforts are also being made to develop artificial cartilage to repair damaged joints.

Systemic Lupus Erythematosus: Systemic lupus erythematosus (SLE) is a chronic inflammatory disease involving several organs of the body. More than 500,000 people in the United States are estimated to have this disease; most are young women. Although its cause is unknown, SLE is considered to be an autoimmune disease, characterized by excessive production of antibodies directed against the body's own tissues. In SLE, autoimmune antibodies have been shown to damage kidneys and other organs, attack brain cells causing convulsions and psychosis, lead to clotting phenomena which cause spontaneous abortions, or cross the placenta and cause heart and skin defects in newborn infants. Using monoclonal antibodies to seek out these destructive antibodies, investigators are uncovering fundamental genetic defects in SLE and facilitating the development of a sensitive test for identifying and monitoring disease activity in SLE.

With improved early diagnosis and more efficient drug therapy, the past several years have witnessed a heartening trend toward improved survival in SLE. Further progress is anticipated through development of innovative forms of therapy by agents which manipulate the immune system.

Lyme Disease: Solving the entire puzzle of Lyme Disease took researchers only some seven years; their success in piecing together the clues provides an excellent illustration of the importance of both basic and clinical research in characterizing a disease. This disease was first identified in 1975 in youngsters as an acute arthritis, followed in some by a chronic, destructive arthritis resembling rheumatoid arthritis. It was preceded in most by spreading skin lesions (erythema chronica migrans). NIAMS-supported investigators discovered in 1978 that the disease is transmitted by a tick; and by 1980 that antibiotics could effectively treat the disease. The cause of Lyme Disease was pinned down when scientists isolated the spirochete (a bacterium) first from the tick and then from patients with Lyme Disease. A blood test for antibodies against the spirochete has been developed. This definitive linkage of a form of arthritis with an infectious agent has served as a major impetus to identify additional forms of arthritis caused by infection.

Osteoporosis: Osteoporosis, a decrease in bone mass, affects as many as 15 to 20 million Americans, especially post-menopausal women and the elderly. Each year, 1.3 million fractures are attributable to osteoporosis, generating an economic burden estimated at $3.8 billion annually. In normal bone remodeling, as new bone is built, existing bone is resorbed continuously. In osteoporosis, an imbalance in this process leads to the production of porous, weakened bone which is highly susceptible to fractures. Two leading causes

of osteoporosis are deficiency of estrogen and deficiency of calcium. Research is ongoing to develop the safest and most effective hormone replacement (estrogen and/or progestin) therapy, and the optimal amount and form of calcium for prevention of bone loss and fractures. Adequate levels of vitamin D, and weight-bearing exercises are also beneficial. Basic research on bone metabolism is greatly needed to discover new ways to stimulate new bone formation, and then be able to treat osteoporosis, once it has developed.

Paget's Disease: Paget's Disease is a major medical problem affecting a large number of people, mostly elderly. In Paget's Disease, the cells responsible for bone resorption function abnormally; this results in mechanically weak and misshapened bones. Recent evidence suggests that Paget's is the result of a slow virus infection. Confirmation and isolation of this virus, as well as research on other hypotheses, are necessary to develop specific therapeutic and prophylactic measures for this disorder. In the meantime, recent studies of treatment with calcitonin and diphosphonates have been very encouraging.

Osteogenesis Imperfecta: Osteogenesis imperfecta is a genetic disease that causes fragile bones leading to fractures in infants and children. Estimated to affect 30,000 people in the U.S., it is the most common heritable disorder of connective tissues. In severe cases, bone fractures may occur even in the fetus. In spectacular research employing the techniques of modern molecular biology, investigators have identified several specific defects in the genetic coding of collagen, the major structural protein of connective tissues.

Low Back Pain: Impairments of the spine are the most common cause of limitation of activity among persons 17 to 45 years of age. Low back pain affects 50 to 80 percent of adults in the U.S. Its total economic impact exceeds $10 billion annually. Both the etiology of low back pain and its optimal treatment are uncertain. The complexity of the back's anatomic supporting structures and nerve pathways have made research on low back pain difficult. The Institute intends to bring together multidisciplinary research teams with expertise in bones, nerves, discs, and muscles to construct research plans directed to this important problem.

Exercise Physiology: With increased national interest in exercise and physical fitness, NIAMS is promoting research on characterizing the responses of muscles, tendons, and ligaments to various forms of exercise and physical training. These basic studies will produce knowledge valuable for the development of optimal rehabilitative programs and the design of more efficient training programs for athletes and others interested in musculoskeletal fitness. This program will aim to define types of exercise which are helpful or harmful for muscles, bone, and other supporting tissues.

Joint Replacements: These operations, usually of the hip, knee, and fingers, are effective in relieving pain and improving joint function, and are reported to have a success rate as high as 90 percent 10 years after implantation. This success rate and the durability of the replacement joints are expected to improve as a result of changes being developed and implemented in the way joints are designed, manufactured, and implanted.

Epidermolysis Bullosa: Epidermolysis bullosa (EB) is a group of tragic, painful, disfiguring and disabling genetic disorders occurring in children. EB causes the skin and other surfaces, including the mucous membranes of the gastrointestinal and respiratory tracts, to blister and become denuded, raw, and scarred. In many cases, the disease resembles a severe burn. As many as 20 forms of EB have been described; some are fatal early in childhood, and many are severely disabling. Newly developed techniques are providing highly important information on the basement membrane zone, the specific region of the skin where the pathology of EB is located, and on new methods to establish an accurate diagnosis of this and related diseases. Research has associated EB with mutations which produce an abnormality in collagenase, the enzyme that breaks down collagen. This fundamental understanding of the disease process has led investigators to treat EB patients with the drug phenytoin (or Dilantin), which blocks the action of collagenase. Dilantin reduces blistering in more than half of patients with EB. NIAMS is making vigorous efforts to strengthen research on EB.

Contact dermatitis: Contact dermatitis is the most common of the immunologic diseases affecting the skin. It comprises the largest single cause of industrial and occupational diseases. Recently, the cellular and immunologic bases for these allergic phenomena have become better understood. Application of this new knowledge may provide the means of impeding their induction.

Vitiligo: Vitiligo, stark white patches of skin, is a poorly understood disease which can cause severe cosmetic disfigurement, serious psychological stress, and interfere with employment, especially in dark-pigmented persons. Thought to be caused by an autoimmune process which destroys an individual's own pigment cells, the disease is characterized by irregular colorless areas of skin. Exploration of this autoimmune hypothesis may create opportunities for blocking the disease process.

Pemphigus vulgaris: Pemphigus vulgaris is a terrible blistering disease that previously carried a high mortality. Autoantibodies directed against skin components have been discovered in high titer in the serum of patients with pemphigus. Recently, it has been clearly established that these antibodies actually cause the blisters of pemphigus to form. Treatment with cortisone-like or other immunosuppressive drugs have made this otherwise dangerous disease more manageable and has been life-saving.

As we move to establish this new Institute, we will work together to develop a comprehensive strategy to quicken the pace and productivity of our efforts. This plan will place heavy emphasis on exploiting the benefits of the most sophisticated techniques of molecular biology, immunology, cell biology, and genetics. It will provide for training the next generation of research scientists, and attracting established investigators to these fields. Teams of investigators will be assembled to conduct multidisciplinary research on the most elusive problems we face in arthritis and musculoskeletal and skin diseases. Attempts will be made to strengthen the resources we already support. Finally, the Institute will work to improve accessibility--by researchers, health practitioners, and the public alike--to the results of our basic, clinical, and epidemiologic research.

Mr. Chairman, the 1987 budget request for this Institute is $106,733,000. I will be happy to answer any questions.

Biography of Dr. Lawrence Shulman

July 25, 1919. Boston, Massachusetts

Education: Harvard University, A.B., 1941; Yale University Graduate School, Ph.D., 1945; Yale University School of Medicine, M.D., 1949.

Professional History: 1949-50, Intern, Medicine, The Johns Hopkins Hospital, Baltimore, Maryland. 1950-51, Ayerst, McKenna and Harrison Fellow in Endocrinology, The Johns Hopkins University School of Medicine. 1951-52, Vernon D. Lynch Fellow in Internal Medicine, The Johns Hopkins University School of Medicine. 1952-53, Assistant Resident, The Johns Hopkins Hospital. 1954-present, Physician, The Johns Hopkins Hospital. 1955-75, Director, Connective Tissue Division, Department of Medicine, The Johns Hopkins University School of Medicine. 1960-66, Physician-in-Charge, Arthritis Clinic, The Johns Hopkins Hospital. 1956-67, Physician-in-Charge, Connective Tissue Clinic, The Johns Hopkins Hospital. 1966-69, Physician-in-Chief, Division of Chronic and Community Medicine, The Baltimore City Hospitals, Baltimore, Maryland. 1970-73, Associate Professor of Medical Care and Hospitals, The Johns Hopkins University School of Hygiene and Public Health. 1964-present, Associate Professor of Medicine, The Johns Hopkins University School of Medicine. 1976-80, Acting Associate Director for Arthritis, Musculoskeletal, and Skin Diseases, National Institute of Arthritis, Metabolism, and Digestive Diseases. 1980-83, Associate Director, Arthritis, Musculoskeletal and Skin Diseases, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. 1983-1986, Director, Division of Arthritis, Musculoskeletal, and Skin Diseases, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. 1986-present, Acting Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases.

Professional Organizations: American Association for the Advancement of Science, American College of Physicians, American Federation for Clinical Research, American Rheumatism Association (President, 1974-75), American Society for Bone and Mineral Research, The Arthritis Foundation, Brazilian Society of Rheumatology, Carla Curzio Neapolitan Society, Lupus Foundation of America, New York Academy of Science, Pan American League Against Rheumatism (President, 1982-86), Society for Clinical Trials, Society for Investigative Dermatology, Sydenham Society, United Scleroderma Foundation.

Honors, Awards: Senior Investigator Award, The Arthritis Foundation, 1957-62. Pemberton Memorial Lecture, 1963. Fellow, American College of Physicians, 1967. The Heberden Medal for Research in The Rheumatic Diseases, Heberden Society, London, 1975. Distinguished Service Award, The Arthritis Foundation, 1979. Honorary Member, Brazilian Society of Rheumatology, 1980. Honorary Member, Australian Rheumatism Association, 1985. The Public Health Service Superior Service Award, 1985.

SUMMARY STATEMENT

Dr. SHULMAN. I do have with me Mr. Laurence as our Executive Officer.

Mr. Chairman and Senator Proxmire, as you can well imagine, it is a privilege and honor for me to appear before you and provide testimony for the first time on behalf of this new Institute, and to share with you some of the research advances and selected scientific opportunities in these fields.

You, the Congress, and the President recognized the importance of these research areas with the enactment of Public Law 99–158, which established this new Institute to devote particular attention to the scientific research in the three areas of arthritis and musculoskeletal and skin diseases. I emphasize the title because we have three major fields, at least, within this new Institute.

In each field there are many different diseases, 100 different types of arthritis, even more skin diseases, and numerous orthopaedic conditions. In each field there are promising research advances. There are some common scientific themes throughout. However, in each field there are different scientific agendas.

I would like to discuss briefly with you this morning 3 of the 14 diseases that I have reviewed in my written testimony, and then make a couple of generalizations at the end, if I may, please.

First, we have new directions for research in rheumatoid arthritis, which as you know is a major crippler. Excellent research previously has indicated that we are dealing with an autoimmune disease that has a predilection for joints, caused by a cascade of immunologic events, and that there was also a role for mediators of inflammation. That is what the cause of rheumatoid arthritis was, it was considered to be basically an immune-mediated disease.

We now have two lines of evidence that rheumatoid arthritis may be caused by one or more infectious agents. First, we have new research findings implicating several microorganisms. We have three candidate viruses: One, Epstein-Barr, or EB virus that we talked about 2 years ago; two, parvovirus, a small virus, we discussed with you last year; and three, there is now a report in the New England Journal of rubella—German measles—virus being implicated in rheumatoid arthritis. We have continuing research on mycoplasma. We also have a very interesting arthritis model, investigated by Dr. Ronald Wilder in our intramural program, a model in which if he takes the fragments of bacterial cell walls and injects them into suitable experimental animals, he can produce, first, an acute arthritis, followed by a chronic arthritis. This work is also being done by Dr. Schwab and his associates in North Carolina.

Last, as you very well know, Senator Weicker, the spectacular story of discovering spirochetal bacteria as the cause of Lyme arthritis has encouraged the search for similar types of organisms in other forms of arthritis. Lyme disease produces acute arthritis, and then in some susceptible individuals, a chronic arthritis resembling rheumatoid arthritis.

The second line of evidence is that we have a new model of rheumatoid arthritis in certain inbred strains of mice, MRL/l mice. These mice regularly develop swollen joints—they are very impressive to look at—beginning at 3 months of age, evolving through 6 months of age. These mice also develop high titers of rheumatoid factors in their serum. The researchers at the University of Alabama, where this research is being done, found that the earliest lesion in the MRL/l mice was proliferation of the joint lining cells. Then there was beginning destruction of the joint cartilege before any signs of inflammation took place. This, therefore, is a new development. We are looking for what virus might be initiating this process in the joint lining cells.

A second important research area is that of osteoporosis. Osteoporosis provides an unusual opportunity for prevention. As you know, we had an NIH consensus conference on osteoporosis in 1984, which generated a lot of scientific information and created a lot of public interest. We learned many things; first, that low dose estrogen had been shown to be effective. Estrogen is a multifaceted, important issue as to whether or not postmenopausal women should take it. Second, it seems that we are not taking in enough calcium. Third, exercise with gravitational stress is very important. In other words, walking is better than is swimming for the bones. There were some experiments performed on our astronauts that speak to that particular question: they lost calcium in space.

We have several questions, however; how best to give these female hormones; how the calcium should be given, there is much controversy about this. We have no treatment—adding new bone—for the osteoporosis, once it has developed. For this purpose we are working on trials with fluoride, and then we are working on bone growth factors. Dr. Löe mentioned one of these, osteogenin, to you in his testimony the other day and there are others.

I also want to report to you that there is a new voluntary agency devoted to this disease, the National Osteoporosis Foundation, organized and chaired by Dr. William Peck and the Honorable Paul Rogers.

The third important area is that of osteoarthritis which is the most common form of arthritis; it affects some 16 million Americans. We have some good beginnings here. We had an excellent conference on osteoarthritis this past summer. There are two misconceptions about osteoarthritis. One is that osteoarthritis is an inevitable consequence of aging, that isn't so. Chemical changes in the cartilage in osteoarthritis are different from the chemical changes in the cartilage in aging.

The second is that this form of arthritis is necessarily caused by wear and tear on the joints. Joe Namath has football knees, but perhaps you may have read about the study that was reported in last Friday's Washington Post. It came from Stanford, and was developed there in one of our arthritis centers. They studied long distance runners who were in the senior group, ages 50 to 72 years of age, and found that these long distance runners had no more evidence of osteoarthritis, either by physical examination or by x ray, than mature nonrunners, shall we say. They also found that the runners made more bone than did the non-

runners. I have the article here from last Friday's Post, if you would care to see it.

This is a very interesting area, and I think it is a parallel to the comment that you, Senator Proxmire, previously made about the Harvard alumni, and how well the exercisers among them are doing. This leads me to the last two generalizations.

The first is that we have great interest in vital basic research in this new Institute in immunology and other scientific areas, but pervading throughout our fields is the study of connective tissues themselves. Connective tissue research is very, very important to the new Institute.

The second is a new objective of this new Institute, which is to provide the science base that will yield the essential knowledge with which we can make some important recommendations about musculoskeletal fitness.

We would hope that with all the increasing public interest in musculoskeletal fitness that we could develop some very important science: and, furthermore, that this might act as a very nice companion piece, if we are successful, to the important work on cardiovascular fitness that the Heart Institute has done such a beautiful job on.

That, sir, is our testimony. The budget for fiscal year 1987 for the new Institute is $106,733,000, and I will be happy to try to do my best to answer your questions.

Senator WEICKER. I have questions to be submitted for the record since we have to move along, and I will only ask one. I will let Senator Proxmire ask his questions.

Clinical trials, did you have any scheduled for this year that will not take place?

Dr. SHULMAN. For fiscal year 1987?

Senator WEICKER. Yes.

Dr. SHULMAN. Yes, sir; there are two. One is on dilantin phenytoin; this is an agent that has shown great promise in the treatment of this terrible disease epidermolysis bullosa. In early trials, it has been found to be effective for the skin disease, but as you know it also affects the gastrointestinal tract, the mucous membranes, and produces esophageal disease. So a trial has been proposed to study this agent, dilantin, in esophageal abnormalities of epidermolysis bullosa.

Senator WEICKER. That has been canceled?

Dr. SHULMAN. That will have to go on hold, sir.

Senator WEICKER. All right, it is on hold.

Dr. SHULMAN. The second one, Senator Weicker, is to——

Senator WEICKER. More to the point, I will tell you right now, it was on hold, as were everybody else's clinical trials. You just leave that to me.

Dr. SHULMAN. The second one would be using retinoic acid, which has been found to be very useful in the treatment of acne. We have a proposed trial of that in scaling conditions.

Senator WEICKER. Senator Proxmire.

Senator PROXMIRE. Dr. Shulman, last year, Dr. Wyngaarden told us that the use of tetracycline in the treatment of arthritis was being evaluated in four animal models. Dr. Wyngaarden went on to say that if the results are encouraging, the use of tetracycline on human models would follow. What is the present status of your animal model testing?

Dr. SHULMAN. Those experiments are in progress, sir, and the results will be available in 1 to 2 years in terms of the final evaluation of that. We have two groups of investigators who are working on this research.

Senator PROXMIRE. Is your Institute evaluating the effectiveness of the use of tetracycline on humans by Dr. Brown and others?

Dr. SHULMAN. Let me give you an update on Dr. Brown's research. We, as you know, have been in close touch with Dr. Brown and Dr. John Hicks, who is his new colleague. They have submitted a grant application, which came to us last summer. It was given a very thorough review by a very good study section. It was not approved, and it was not approved for two very specific reasons, which are both easily remedied.

We have been in discussion with Dr. Brown and Dr. Hicks, and their supporters also; they are in the process of revising their application in accordance with the recommendations of the review group. They have agreed with these recommendations, and are coming back with a revised application.

Senator PROXMIRE. I just have one more question. On page 5 of your statement, you talk about exercise physiology. You say: "These basic studies will produce knowledge valuable for the development of optimal rehabilitative programs and the design of more efficient training programs for athletes and others interested in musculoskeletal fitness." I wonder what priority we ought to give training programs for athletes?

Dr. SHULMAN. What do you think?

Senator PROXMIRE. I am not going to make any recommendation to you. I think that your judgment on this is good. I would like to see how exercise can help people who are ill and suffering from disease, rather than people who are healthy and want to know how they can build bigger biceps.

Dr. SHULMAN. I think we are interested in both.

Senator PROXMIRE. Why are we interested in people who are normally healthy and interested in building up their muscles?

Dr. SHULMAN. I think that it is part of the mandate of the new Institute. There is specific language in the new Institute that speaks to the question of athletic performance, as well as athletic injuries.

I agree with your point. Your point is very well taken.

Senator PROXMIRE. Maybe I am thinking too much about the salaries paid to many athletes as compared to poor Senators.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. There are further questions for response to the record. I look forward, Dr. Shulman, to working with you.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

ADMINISTRATIVE COSTS

Question. During the debate concerning the creation of this new Institute, the point was made that the cost of a new administrative structure would take money away from research. How much administrative funding was necessary when you were part of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK)?

Answer. In 1985, the costs for the Arthritis, Musculoskeletal, and Skin Diseases extramural program staff and the National Arthritis Advisory Board were $1,755,000. These programs shared with all other extramural programs of the NIADDK the services of the grants management and contracts management offices, as well as the administrative services of such offices as personnel, budget, program planning, and public information. These shared management and administrative functions cost $13,707,000 in 1985.

Question. How much additional funding is now necessary to staff the administration of this new Institute?

Answer. It is estimated that ultimately an additional $3.2 million will be needed beyond the administrative costs directly transferable from the parent Institute.

Question. Does your FY 1987 proposal add this money or will you have to take it from other programs?

Answer. The 1987 President's Budget Request provides $1.0 million of the non-transferable administrative costs needed to complete the first phase of establishing the new Institute's administration.

FUNDING LEVELS

Question. When you were part of the NIADDK, what were the overall funding levels for both extra and intramural research on arthritis?

Answer. In 1985 the actual obligations for all research within the Arthritis, Musculoskeletal, and Skin Diseases Division totaled $100,575,000 in extramural support, $6,478,000 in conduct of intramural research, and $1,755,000 for direct administrative expenses. In the current year, FY 1986, we estimate that extramural research in the Division will total $101,554,000, intramural research will total $6,189,000, and direct administrative expenses will be $2,045,000.

Question. Given the overall reductions in the FY 1987 budget request for NIH, has funding for arthritis research been reduced due to the extra administrative expense of setting up the new Institute?

Answer. In order to provide for the administrative overhead expenses associated with the establishment of the new Institute, adjustments were made in the overall NIH allowance.

COST OF DISEASE VS. COST OF RESEARCH

Question. Arthritis and related bone diseases affect over 44 million Americans and have been estimated to cost our economy, in both treatment and loss of productivity, in excess of $114 billion per year. How much are we spending on arthritis-related research?

Answer. Research on arthritis and related musculoskeletal disorders by the National Institute of Arthritis and Musculoskeletal and Skin Diseases totaled $65,623,000 in FY 1985, is estimated to be $65,400,000 in FY 1986, and is estimated to be $63,800,000 within the President's 1987 Budget request. For all of the NIH Institutes which support research in arthritis and related musculoskeletal diseases, total 1985 support was $100,470,000, the total in 1986 is estimated to be $99,563,000 and the President's 1987 Budget would support $97,078,000.

Question. How much more would it cost if we followed every reasonable research opportunity in this area?

Answer. During the preparation of the 1987 Preliminary Budget Report to NIH, we were given the opportunity to express our opinion on this subject. A total budget of $146,385,000 for the new NIAMSD would allow aggressive pursuit of scientific opportunities in all mechanisms of support. In addition, the $3,200,000 needed for establishing the administrative structure of the new Institute, which had not been authorized at the time of the Preliminary Budget, would bring the total to $149,585,000.

Question. Can you provide us with an example of a new or promising research breakthrough or treatment?

Answer. Infectious agents have long been conjectured to play a role in the development of arthritis. Potential candidates include viruses, mycoplasma and other bacteria. A three-year study has led to a recognition of the possibility that parvoviruses may play a role in the etiology of human rheumatoid arthritis. Independent confirmation must now be obtained from studies designed to show a relationship between the virus and the clinical, pathologic, and immunologic characteristics of rheumatoid arthritis. Research on other candidate viruses is in progress.

Question. Are you asking for enough funding to follow this line of investigation at maximum effort?

Answer: Research on the role of viruses in arthritis is being conducted at approximately the 1985 level. The President's Budget Request for 1987 includes sufficient funding to continue most of this valuable work, and we are optimistic about the possibilities for further advances in this field.

Question. How much more will be necessary?

Answer. Almost any area of research can be expanded if extra resources are devoted to it, given the substantial number of approved research project grant applications which remain unfunded each year. Given the serendipitous nature of research, one can never say with

assurance that additional funds will lead to a breakthrough in a particular field of study.

RESEARCH PRIORITIES

Question. Can you describe the criteria that will be used to determine the priorities and resource allocation for the areas of research on arthritis, musculoskeletal and skin diseases?

Answer. Determination of research priorities is dependent on several factors including appropriateness and availability of a clinical and basic science research base, existence of trained investigators, and identification of a problem as a significant health issue. Resource allocation is based, to a large extent, on the assessment of scientific merit as determined by the NIH's peer review system.

Question. What are the leading priorities in these three areas?

Answer. The fields of arthritis and musculoskeletal and skin diseases offer a variety of numerous potentially fruitful research possibilities. Examples include:

Arthritis: Studies of the possible infectious etiology of early arthritis may be especially appropriate for pursuit at this time due to development of new research methodologies which enhance the opportunity for identifying microorganisms, or their antigenic products, in tissues. There is special interest, with respect to rheumatoid arthritis, in agents such as mycoplasmas, Epstein-Barr virus, and parvovirus. In the spondyloarthritic group of rheumatic diseases, candidate agents are Salmonella, Shigella, Klebsiella, Yersinia, and Chlamydia. Other areas of emphasis include immunogenetics and the immune expression of rheumatic diseases. While numerous advances have been made in immunology, our knowledge of the precise pathogenetic roles of immunological events in many rheumatic disorders remains still incomplete. Further efforts are needed to relate what is known in basic immunology, both cellular and humoral, to the pathophysiology of specific rheumatic diseases.

Musculoskeletal Diseases: Osteoporosis is a common disease that weakens bones and makes them susceptible to fracture. The economic impact exceeds $6 billion. Preventive measures will receive the highest attention. A workshop is planned for January 1987. Osteoarthritis is a leading crippling and disabling disorder in the broad range of arthritic conditions. A large productive workshop was held in 1985, and many new research directions were formulated. A workshop summary will be published in a major journal and will help greatly to stimulate new research proposals. Low back pain is another significant medical problem experienced by the majority of Americans. The economic burden exceeds $10 billion. A workshop to encourage and focus new directions in research will be held in 1987. Sports medicine science is important because the number of exercising Americans is rapidly increasing. A strong science base needs to be developed as a basis for future advancements. The program staff are gathering recommendations from the leaders in various sports-related disciplines.

Skin Diseases: There are numerous research opportunities in cutaneous biology and cutaneous diseases. There is needed general support of investigator-initiated research projects in the skin disease areas, with specific emphasis on the use of modern techniques of molecular biology, molecular genetics, and immunology as they apply to the normal structure and function of skin and the changes with disease. We also need continued expansion of our research effort in epidermolysis bullosa and the biology of the basement membrane zone, both in terms of basic science research and support of an EB Registry designed to assist investigators interested in this area of research.

IMMUNOLOGY

Question. I understand that faulty immune mechanisms have become strongly implicated as a factor in arthritis. Can you bring this Committee up to date on these findings?

Answer. Research during the past several years has clearly shown the involvement of the immune system in arthritis in its various forms. One significant finding has been the association of certain of the rheumatic diseases with genes of the major histocompatibility locus in man. These genes are responsible for controlling the immune response. The manner in which these genes function, however, still remains unclear. For example, although 90 percent of patients with ankylosing spondylitis may be of the HLA-B27 type, only a very small percent of all people who have B27 actually develop this disease. The presence of HLA-B27 is therefore not the sole determinant in causing the disease: there must be other factors. Other arthropathies, psoriatic arthritis and some forms of juvenile rheumatoid arthritis are associated with the HLA-D genetic region. There is increasing evidence that important abnormalities exist in the genetic, humoral immune, and cellular immune systems of patients with systemic lupus erythematosus. An understanding of the nature of these associations, the role they play in disease susceptibility, and the significance of immune response genes are among the most important and challenging problems in medicine.

Question. What kind of cooperation exists between the other institutes that support immunological research, and has the creation of this new Institute enhanced that cooperation?

Answer. Strong cooperation among the Institutes has been forged under the aegis of the Arthritis Interagency Coordinating Committee whose members derive from all the existing Institutes at NIH plus all other federal agencies with rheumatic diseases interest. Creation of the NIAMSD will sharpen the interest in immunological research and better understanding of rheumatic disease.

OSTEOPOROSIS

Question. Osteoporosis is a disease that affects 15-20 million Americans (mostly women) and costs our economy about $4 billion each year. Can you update this Committee on the progress of your research efforts, and are there any promising advances on the horizon?

Answer. We support a large program in osteoporosis and related research in basic bone metabolism. A new comprehensive study was recently supported (and co-sponsored by NIA) to evaluate risk factors for hip and Colles' (wrist) fractures. This study may help to identify more clearly high risk populations and promote earlier intervention. New projects have been started to determine factors that influence the strength of bone that is osteoporotic. The structural quality of bone may be more important than the quantity of bone.

A large clinical trial on fluoride treatment in osteoporosis is ongoing; results will be available when the trial is fully completed. A recent study in Finland of towns with and without fluoridated water supplies shows less hip fractures in the fluoridated town. This may be a promising additional benefit to the fluoride already added for dental caries prevention.

Calcitonin, a hormone currently used with a moderate degree of success in treating osteoporosis, may soon be improved by a new nasal mist delivery system that may be more beneficial and more convenient than previous forms.

Question. How much are you spending for research in this area?

Answer. In 1985, the National Institute of Arthritis and Musculoskeletal and Skin Diseases supported $4,424,000 in osteoporosis research. During 1986, it expects to spend approximately $4,895,000 in this field, and within the 1987 request expects to support approximately $4,760,000 for osteoporosis research.

LYME DISEASE

Question. Lyme, Connecticut has had the misfortune of contributing its name to a form of arthritis known as Lyme Disease. I know you have been able to identify the cause of the disease. Can you provide us with an update on its treatment?

Answer. Patients with the early skin lesion of Lyme disease (Erythema Chronicum Migrans) took part in treatment trials conducted by NIADDK grantees at Yale University School of Medicine. These trials established that early antibiotic therapy can prevent the late complications of the disorder. A 10- to 20-day course of tetracycline was found to work best for adults; penicillin or erythromycin was recommended for children. These trials showed that early antibiotic treatment can prevent the progression of the disease to the late stage of chronic Lyme arthritis.

In another study, these same investigators treated 12 patients who had neurologic problems such as meningitis from Lyme disease, by using high doses of intravenous penicillin. This approach also proved successful; and there were no relapses.

Still another new finding is that treatment of established arthritis in this disease is possible, based on the results of a double blind, placebo-controlled trial. Intramuscular penicillin in high doses was given to 20 patients with Lyme arthritis, eliminating the arthritis and preventing any further arthritic attacks

in 7 of the 20. These patients have remained well over an average follow-up period of 33 months.

Question. I understand that Lyme Disease is caused by the introduction of a parasite through the bite of a tick. Has any work been done in the area of prevention?

Answer. It is clear that hundreds of new cases of Lyme disease occur each year. It is necessary for physicians to know how to diagnose and treat the infection. For public health officials, it is important to conduct surveillance, provide serologic support, disseminate information, and to consider methods of tick control.

Prevention is difficult. Of the various animals in the wild that harbor the tick, wild deer, important in the life cycle of the tick, seemed amenable to interventions that might control the tick. After attempting to treat the wild deer population of Great Island, Cape Cod, Massachusetts, with pesticides, 70 percent of the deer were eventually removed. The pesticides used were not highly effective, and deer removal, to the extent accomplished, did not markedly reduce the abundance of the ticks. Some vaccine work with animals is being done with domestic pets. There are regional differences in the country where the ticks seem to be less important in the transmission of the disease and at least one area where the tick is not associated with deer as hosts. Other tick-borne diseases have not been dealt with in a highly successful manner using preventive measures to control the tick.

EPIDERMOLYSIS BULLOSA

Question. Each year during our public witness hearings we are visited by Cal Larson who is suffering from Epidermolysis Bullosa. Can you bring us up to date on any progress in understanding this disease and its treatment?

Answer. There has been significant progress in epidermolysis bullosa (EB). There is increasing understanding of the specific genetic types of EB which now number 18 or more. There is also increased understanding of the specific molecular and genetic defects among the various clinical forms of EB, with emphasis on the severe recessive dystrophic form. The abnormal collagenase enzyme that is present in this disease has been isolated and the gene for it has apparently been cloned, although the evidence is still preliminary. Structures called "anchoring fibrils," which are defective in dystrophic forms of EB, both recessive and dominant, have been discovered to be type VII collagen. There is an ongoing FDA-supported study to evaluate the efficacy of dilantin in selected forms of EB.

There are investigations of other drug treatments for different forms of EB, including antibiotics and specific types of dressings once the wounds have taken place. We expect that the establishment of the EB Registry will assist in further productive studies on EB.

Question. Is there anything I can tell young Cal this year?

Answer. We can tell young Cal this year that we are learning more about EB, there is heightened interest in research on EB, and that all of the most modern tools of biomedical research are being

brought to bear in these studies of EB. They have already uncovered many new and interesting facts which, we hope, will have a direct bearing on the treatment of his disease.

Question. How much money is being spent on research for EB?

Answer. In 1985, we supported $2,216,000 in epidermolysis bullosa research. During 1986, we expect to support approximately $2,934,000 in this field, and within the 1987 request expect to spend approximately $2,853,000 on epidermolysis bullosa research.

OSTEOGENESIS IMPERFECTA (BRITTLE BONE DISEASE)

Question. Last year we were told that the genetic defect causing osteogenesis imperfecta (brittle bone disease) had been identified, and this was considered major progress. What can you report to us now -- have we made additional progress?

Answer. Progress has continued in determining specific genetic defects in osteogenesis imperfecta (OI). The problem is complex because there are many forms of osteogenesis imperfecta and many genetic defects to be expected in view of the complexity of the collagen molecule. Further identification of defective collagen formation has been documented, and to additional specific sites.

Question. Dr. Lipsett indicated that there was some difficulty in attracting good scientists into this field. Have you developed a plan to solve this problem?

Answer. In February 1985 a Program Announcement was released requesting additional research in osteogenesis imperfecta (OI). Several investigators have discussed specific research projects with NIAMSD staff. A few promising research grant applications have now recently entered the review system.

Question. Given the President's request for your training budget, how do you plan to deal with this problem in all areas of research?

Answer. Attracting high-quality scientists to work in the areas of arthritis, musculoskeletal and skin diseases continues to be an Institute priority. There has been a gratifying increase in the number and quality of applicants for research training and career development awards of young investigators. Applicants are encouraged to apply for the most appropriate training vehicle for their career objectives and training level. We are also cooperating with other sources of training funds, such as the voluntary health agencies and other non-profit organizations, to coordinate training opportunities. Scientists may also be trained as research associates on already-funded projects of more senior investigators.

LUPUS ERYTHEMATOSUS

Question. PL 99-158 requires that a coordinating committee on lupus be set up chaired by the Director of the Institute. Can you tell us if this Committee has been set up and describe for us its agenda?

Answer. Public Law 99-158 requires that the Lupus Erythematosus Coordinating Committee render an extensive report to Congress 18 months after enactment of the Act. This Committee will be established by the Acting Director of the Institute shortly. One of the principal items on the agenda of the Committee will be preparation of a report describing research projects conducted or supported by Federal agencies, the nature and purpose of each project, the amounts expended for each project, and identification of each entity which conducted the research under each project.

Question. How much is now known about this disease, and can we expect any breakthroughs in its treatment or a cure in the forseeable future?

Answer. Although the etiology of systemic lupus erythematosus is unknown, it is widely held to represent a complex disorder of immunoregulation. Treatment with corticosteroids and immunosuppressive drugs has been very effective for the most part. Unfortunately, some patients with lupus are still refractory to such therapy. Many innovative therapies are being proposed and evaluated in experimental models of lupus in inbred mice. Different strategies for a specific therapy are being developed. One entails regulation of the antibody itself. Attempts to control the production of anti-DNA antibodies by means of anti-idiotypic antibodies to anti-DNA antibody have been described. A monoclonal anti-idiotypic antibody has been used with success to treat SLE in mice. The other therapeutic approach is to induce immune tolerance to DNA.

GRAMM-RUDMAN-HOLLINGS

Question. If the automatic provisions of Gramm-Rudman-Hollings are triggered in FY 1987, your Institute may well have its budget reduced by 20-25%. Have you prepared a contingency plan in the event Gramm-Rudman-Hollings becomes reality? If so, please send a copy of your plans to this Committee.

If cuts of this magnitude become reality, how will they be distributed:

1. Intramural vs. extramural programs;

2. Peer review system;
   Would number of site visits be reduced?
   Would travel to NIH to study section meetings be affected?

3. Would NIH employees have to be furloughed?

4. What major programs would have to be cut back?

Please list the research programs of the highest priority that should not be cut and why.

Answer. At this time the NIH has not developed a specific sequestration plan for reductions below the amounts requested in the FY 1987 President's Budget. In compliance with the provisions of the Gramm-Rudman-Hollings Act, the President's Budget was developed within overall deficit targets which would preclude the need for any sequestrations in FY 1987.

However, if NIH were to sustain further cuts in the 20-25 percent range, all programs would be affected to some degree and serious consideration would have to be given to eliminating certain programs. A careful review of all programs would need to be conducted before such decisions would be made.

IMPACT OF BUDGET REDUCTIONS

Question. The President's budget proposal for FY 1987 reduces your budget by $33,700,000 under FY 1986 appropriated levels. Gramm-Rudman-Hollings, if triggered, could reduce your budget even further maybe by as much as 20 percent.

I have known this would reduce the number of grants, possibly the size of grants, centers, training, etc., etc.

Can you give us some idea of the impact of these reductions on the kinds of research that would be stopped or lost?

and,

What impact might this have on the health of our citizens five and ten years down the road?

Can you discuss your contingency plans if these massive budget cuts should come to pass?

Answer. At this time, NIH has not developed a specific contingency plan for further sequestrations below the amounts currently requested in the FY 1987 President's budget. However, if NIH were to sustain further cuts in the range of 20 percent, it is safe to assume that all programs would be affected to some degree. As part of a careful review of various options, serious consideration would also have to be given to eliminating certain research activities.

With regard to the impact of further funding reductions on the health of our citizens, it is impossible to project or quantify precisely the consequence of differing research funding levels on the Nation's health in future years. Nevertheless, reductions in the order of 20 percent could not be absorbed without significantly reducing the level of biomedical research supported by the NIH and it is this investment which impacts directly on the future availability and efficacy of new health diagnoses, preventions, and treatments.

PUBLIC TESTIMONY VIZ DR. BROWN'S THERAPY FOR ARTHRITIS

Question. This Committee has taken testimony for the past few years from patients who have claimed successful treatment for rheumatoid arthritis. I believe it involves an antibiotic therapy for mycoplasm.

I also understand that the doctor who developed this therapy has applied for a grant to conduct a clinical trial.

What is the status of this proposal?

Answer. Dr. Brown's research grant application was received by NIH several months ago and referred to the Division of Research Grants for scientific review. The review was conducted, including a site visit to Dr. Brown's laboratory by the review team. Upon completion of the review, the application was recommended for disapproval because of two specific problems, both of which can be corrected. The National Arthritis, Diabetes and Digestive and Kidney Diseases Advisory Council concurred with this recommendation. Dr. Brown was notified of the reasons for disapproval, and is revising his application for resubmission.

Questions Submitted by Senator William Proxmire

COMPETING PROJECT GRANTS

Question. Dr. Shulman, I'm curious as to how you decide how much you're going to award an individual investigator. On page 207 of your justifications you indicate that you will award 5.4 percent less for the average competing project grant in 1987 than you will in 1986.

On the other hand the Aging Institute will award 2.1 percent more and the Institute of Child Health the same amount as in 1986. Your Institute will cut recommended levels of support by 12.8 percent while the other two Institutes will make cuts of 10.4 percent and 9.8 percent from recommended levels of funding. Can you explain why you are cutting recommended levels of support more sharply than the other two Institutes?

Answer. Decisions on how much to award to individual investigators are made by the peer review system based on their evaluation of the funds that are requested to support the project. In order to fund the Institute's assigned number of grants, this recommended level must then be reduced to fit the funds available. This reduction is different for every institute.

Question. What factors go into such a decision?

Answer. In building the budget request, NIH sought to allow most Institutes to fund a number of competing research project grants commensurate with their recent history of support. The objective of funding the assigned number of competing grants within the allowances given to the Institutes necessitated differing levels of downward negotiations.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

STATEMENT OF DR. CLAUDE LENFANT, DIRECTOR

NOBEL PRIZE RECIPIENTS

Senator WEICKER. Next we have my good friend, Dr. Claude Lenfant, Director of the National Heart, Lung, and Blood Institute. You may proceed, Dr. Lenfant.

Dr. LENFANT. Thank you, Mr. Chairman.

Because of the pressure of time, I will try to shorten my opening remarks. However, I would like to say that we have had a very productive and exciting year, with many things to report to you. Not least, of course, is the fact that this year two of our grantees were awarded the Nobel Prize for physiology and medicine, as well as the Lasker Foundation Award, for a long series of studies on the metabolism of cholesterol.

The Institute has supported them for about 12 years now. Their prior work was supported by the National Institute of General Medical Sciences. The importance of that work is that it really opens the door to emerging treatment for the less familiar forms of arteriosclerosis, as well as the common form which affects so many people.

CLOT-DISSOLVING DRUGS

Another achievement that I would like to report to you is a followup of something I mentioned last year; the development of a drug which has the possibility to dissolve blood clots that obstruct coronary arteries and cause heart attacks.

In fact, last Monday, in the Wall Street Journal, there was a big story about that, saying how successful the drug has been and is. Prior drugs would enable physicians to open up obstructed coronary arteries in about 30 to 35 percent of the cases. This new drug has a yield of about 85 percent, which is a substantial achievement.

CYSTIC FIBROSIS

Last Wednesday, and again today, you heard a lot about cystic fibrosis. As Dr. Wyngaarden mentioned, this is a line of research which is pursued by several Institutes. I want to mention it also and add one thing which is of special interest to you. Our Institute has contributed to the discovery which has been mentioned twice already, but what you might be interested to know is that the work sponsored by our Institute

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was supported by a grant to a small business organization, where a team of researchers has contributed to this work.

SICKLE CELL DISEASE

Turning quickly to our blood program, this year we have established that prophylactic penicillin treatment in newborn infants with sickle cell disease can almost eliminate the risk of pulmonary infection and septicemia, which are the main causes of death in these infants.

If you add that to the prior development of prenatal screening tests, there is here an opportunity to really make headway in the treatment and prevention of complications in these infants.

AIDS

The last thing that I would like to mention is really a reiteration of what Dr. Fauci mentioned to you last week, when he discussed the AIDS Program at NIH. As you know, our Institute is very much involved, in fact is responsible for all the research on transfusion transmitted AIDS. In this area, too, we have made substantial progress.

Dr. Fauci was mentioning to you last week the discovery of the synthetic peptide which replicates a fragment of the envelope of the virus. The important thing about this achievement is that it opens the door to developing a new and probably more reliable blood test. This synthetic peptide, as was mentioned, has been given to chimpanzees, which in turn have developed antibodies. If these antibodies have neutralizing properties, then the door might be opened to the development of the synthetic vaccine against AIDS.

PREPARED STATEMENT

So, briefly, that is what I wanted to underscore, Mr. Chairman, and I would be pleased to answer questions.

[The statement follows:]

Statement of Dr. Claude Lenfant

I am pleased, once again, to report to you on recent advances in the programs of the National Heart, Lung, and Blood Institute and on opportunities available in cardiovascular, pulmonary, and hematological research.

The Institute is unequivocally committed to support the entire spectrum of research, both basic and applied; both for treatment and prevention. The investment in these areas over the past year has been productive, as illustrated by the advances I will describe. Experience has shown that investigator-initiated research is the foundation of our programs and one of our richest sources of new ideas. Investigator-initiated research merits the highest priority in NHLBI planning. It is also important, however, to continue to identify and support other avenues of research, particularly clinical validation and technology transfer, such as our centers programs and clinical trials. Results of research using these mechanisms have proved invaluable in reducing morbidity and mortality from heart, lung, and blood diseases, in increasing professional and public awareness of risk factors, and in providing community practitioners of medicine with clear indications of whether certain treatments are effective.

New goals should be set in FY 1987, and new avenues of research should be pursued, with tangible implications for the prevention of disease. For example, we now know that atherosclerosis is not necessarily a part of the aging process. In fact, its onset can begin early in life. Techniques and advances in molecular biology and biochemistry will continue to expand basic knowledge about the atherosclerotic process and may lead in the foreseeable future to methods of direct intervention in this disease. The field of pulmonary research has been rejuvenated largely through basic research. For example, we now have a tenable basis for new research approaches to two forms of respiratory distress syndrome. The field of hematology, especially with regard to hereditary red cell disorders, which affect over 180 million people worldwide, has expanded during the last few years. The genetics of clotting disorders is now being clarified and leading to new insights and new treatment opportunities. Transfusion medicine is becoming a recognized medical specialty. Furthermore, we are now developing programs that link these seemingly disparate fields through common research approaches.

Atherosclerosis: Fundamental Investigations

Deaths from cardiovascular diseases account for almost one-half of all deaths in the United States, three-fourths of which are related to atherosclerosis. In our testimony two years ago we described in some detail how plasma cholesterol associated with low density lipoproteins (LDL) contributes to formation of atherosclerotic plaques. It is very gratifying to be able to report that in the fall of 1985, Michael S.Brown and Joseph L. Goldstein of the University of Texas Health Science Center were awarded both the Nobel Prize for Medicine and the Albert Lasker Medical Research Award in recognition of their work in solving the mysteries of the LDL receptor. In the 1970's, the National Heart, Lung, and Blood Institute provided support to Dr. Brown, and the

National Institute of General Medical Sciences provided support to Dr. Goldstein for this work, which originated when these two scientists at an earlier date began their research careers in NIH laboratories. Since 1977, their work has been supported by the NHLBI. They have elucidated the mechanisms involved in the regulation of levels of blood lipids by receptors on the surface of the liver and other cells that bind particles of LDL and remove these from the blood stream. The LDL is taken into the cells where it is broken down and yields its cholesterol to serve the cell's needs. When the receptors are defective, LDL cannot be removed normally and it accumulates to high levels in the blood plasma. The build-up accelerates the atherosclerotic process. Mutations in one of the genes for the receptors can produce heterozygous familial hypercholesterolemia, which is a cause of heart attacks in middle-aged people. In fact, approximately one person in every 500 inherits one such mutant gene for the LDL receptor, and as a consequence may suffer heart attack as early as age 35. About one in one million persons inherits two mutant LDL receptor genes. These persons have extremely high LDL-cholesterol levels, and usually develop heart attacks before 20 years of age. Genetically induced alterations in the LDL receptor have now become the subject of intensive research.

Recently it has become possible to study the molecular genetics of these mutations as a result of the cloning of complementary DNA (cDNA) for the human LDL receptor and the subsequent isolation of genomic clones covering most of the LDL receptor gene. This information would be used to develop insights to the management of the inherited disease familial hypercholesterolemia and methods to intervene and control high blood cholesterol.

Atherosclerosis: Prevention and Education

A large body of evidence, including the results of the Lipid Research Clinics Coronary Primary Prevention Trial (CPPT) that I reported to you last year, has shown that blood cholesterol levels can be lowered safely by diet, by drugs, and by both. In light of this evidence, it is important that health professionals and the public be made aware of the significance of cholesterol as a risk factor for coronary heart disease. Recent surveys of physicians and the lay public suggest that their understanding of this critical information is inadequate. Thus, there is need for a concerted national effort to provide information both to health professionals and to the general public. A recent NIH-sponsored Consensus Development Conference on Lowering Blood Cholesterol developed guidelines for health professionals and the lay public regarding cholesterol levels that should be treated, goals of treatment, and issues relating to the use of diet and drugs. After the consensus conference, interest began to grow for a Federally sponsored National Cholesterol Education Program.

The Institute has now developed and is coordinating such a program, the mission of which is the reduction of coronary heart disease morbidity and mortality attributed to elevated blood cholesterol. This is a national educational effort involving extensive cooperation and coordination with other government agencies and intermediary groups in the private sector. The National Cholesterol Education Program will be operated as a partnership with a wide

range of organizations. The effectiveness of such networking was established by the National High Blood Pressure Education Program, which also encompassed a large number of organizations -- governmental, professional, voluntary, community, private, and educational.

Neonatal Respiratory Distress Syndrome: Lung Surfactant

A lipoprotein-complex called pulmonary surfactant is present in the small air sacs of the lung. This substance reduces the surface tension of pulmonary fluids and thus greatly reduces the work of breathing. Prematurely born infants who are deficient in this lipoprotein complex can manifest a lung disease called respiratory distress syndrome (RDS). The possibility of using artificial or animal-derived surfactant for treatment of neonatal RDS is now foreseeable. Institute-supported investigators working in collaboration with private industry have recently determined the entire sequence of amino acids in canine and human surfactant proteins. Earlier this year, they cloned the gene for human surfactant. By implanting the cloned gene in cultured human cells, scientists can now synthesize large quantities of surfactant protein. In addition to their anticipated therapeutic value, these recent accomplishments will provide molecular probes for future studies to determine the structure and regulation of the gene or genes responsible for surfactant protein, make it possible for investigators to study gene expression during lung development, and generate human surfactant-associated protein for possible clinical use.

Adult Respiratory Distress Syndrome: Therapeutic Regimens

Another type of respiratory distress syndrome is the condition of acute respiratory failure that develops in patients as a sequel to various conditions, including trauma and viral respiratory infections. The high mortality rate associated with adult respiratory distress syndrome (ARDS) attests to the difficulty of finding effective treatments for this condition. The cornerstone of therapy for ARDS is mechanical ventilation with continuous positive airway pressure. Recent basic studies of the action of drugs on inflammatory cells, and experiments testing the delivery of certain enzymes to sites of pulmonary injury, hold the promise that practical, effective forms of treatment will emerge as an adjunct to ventilatory assistance. A class of drugs that may prove useful in treating ARDS are non-steroidal anti-inflammatory agents. The drug ibuprofen, now widely used as an analgesic, has recently been found to suppress many biological activities thought to be associated with development of acute respiratory failure.

An alternative therapeutic approach being tested is the use of systems for delivering quantities of naturally occurring antioxidants to lung tissue. Red blood cells were used as natural antioxidant "capsules" and shown to provide a remarkable degree of protection against oxidant-induced lung injury in several kinds of experiments. This research may have a significant impact on the treatment of this life-threatening disease.

AIDS

Transmission of acquired immunodeficiency syndrome (AIDS) through transfusion of blood or blood components should be greatly reduced now that tests for antibodies to the virus are being used for all units of donated blood or plasma in the United States, and positive units are carefully discarded. In addition, development of heat treatment to inactivate any virus which may escape the screening procedure has resulted in a safer product for hemophiliacs. We continue to support studies to determine what factors increase the risk that transfusion-infected individuals will develop AIDS. We also support the search for antibody fractions that might neutralize the virus, and we plan to support research on other methods to inactivate the virus in blood products.

Red Cell Disorders: Sickle Cell Anemia Treatment

The prompt institution of treatment of the child who presents with life threatening complications associated with sickle cell disease depends on early diagnosis and entry into the health care delivery system. For the system to work as efficiently as possible, a thorough education of the parents must be instituted soon after the diagnosis is made. Preliminary evidence demonstrates that infants with sickle cell anemia who receive immediate care from a knowledgeable provider, combined with measures which reduce the incidence of infection (such as prophylactic penicillin and pneumococcal vaccine) may have a lessened likelihood of early death. In the absence of specific therapy for sickle cell disease, such approaches that prevent complications and crisis offer the best opportunity for optimal care and underscore the importance of newborn screening for sickle cell disease.

Cooley's Anemia

Patients with Cooley's anemia, who must undergo lifelong treatment by transfusion of red blood cells, suffer from the toxic effects of iron accumulation in vital organs, and usually die of cardiac failure. Because transfusion with very young red blood cells (neocytes) minimizes the accumulation of iron, the separation of these young cells from frozen blood has been a scientific challenge. At one center investigators have now been able to prepare neocytes from fresh blood by using a filter to remove white cells and platelets before separating neocytes by centrifugation. Such preparations have now been used for more than 500 transfusions without any adverse reactions reported. Preliminary data also indicate that this method results in a higher concentration of red cells, a decrease in the overall number of transfusions required, and an increase in the oxygen-delivering capacity of the blood. Moreover, the yield of packed red cells and neocytes is 36 percent greater and at a reduced cost compared to use of frozen preparations. These advances hold great promise for less costly, more effective treatment of Cooley's anemia.

This nation's investment in heart, blood vessel, lung, and blood research continues to pay dividends and continues to return benefits for good health. Progress in prevention and treatment of

many heart, lung, and blood diseases has been amply demonstrated in the past year.

Mr. Chairman, the 1987 budget request for the National Heart, Lung, and Blood Institute is $785,697,000. I will be pleased to answer any questions the committee may have.

Biography of Dr. Claude Lenfant

October 12, 1928, Paris, France

Education: B.S., University of Rennes, France, 1948. M.D., University of Paris, France, 1956.

Professional History: 1957-1958, Research Fellow, University of Buffalo, New York. 1958-1959, Research Fellow, Columbia University, New York. 1959-1960, Assistant Professor of Physiology, University of Lille, France. 1961-1965, Clinical Instructor of Medicine and of Physiology and Biophysics, University of Washington, Seattle. 19661967, Clinical Assistant Professor of Medicine and of Physiology and Biophysics, University of Washington, Seattle. 1968-1971, Associate Professor of Medicine and Physiology and Biophysics, University of Washington, Seattle. 1970-1972, Acting Associate Director, Collaborative R&D Program, National Heart and Lung Institute, NIH. 1970-1972, Associate Director for Lung Programs, National Heart and Lung Institute, NIH. 1971-1972, Professor of Medicine and Physiology and Biophysics, University of Washington, Seattle. 1972-1980, Director, Division of Lung Diseases, National Heart, Lung, and Blood Institute, NIH. 1981-1982, Associate Director for International Research, NIH. 1981-1982, Director, Fogarty International Center for Advanced Study in the Health Sciences, NIH. 1982-Present, Director, National Heart, Lung, and Blood Institute, NIH.

Professional Organizations: Association of American Physicians, American Society for Clinical Investigation, American Physiological Society, American Federation for Clinical Research, French Physiological Society, International Federation for Medical Electronics, American Society of Zoologists, Society for Experimental Medicine and Biology, Undersea Medical Society, New York Academy of Science.

Honors, Awards: Thesis Prize, University of Paris, France, 1956. Commendation Tohoku Medical Society, Sendai, Japan, 1973. Superior Service Honor Award, DHHS, 1974. Regents' Professor, University of California, Los Angeles, 1975. Testimonial Dinner, American Thoracic Society, 1979. Honorary Fellow, American College of Chest Physicians, 1979. Honorary Professor, National Yang-Ming Medical College Taipei, Taiwan, 1980. Honorary Professor, Universidad Peruana Cayetano Heredia, Lima, Peru, 1981. Senior Executive Service Performance Award, 1982. Elected Institute of Medicine, National Academy of Sciences, 1983. American Heart Association Scientific Councils' "Distinguished Achievement Award," 1983. Senior Executive Service Performance Award, 1983. Honorary Fellow - Council on Clinical Cardiology - American Heart Association, 1984. Senior Executive Service Performance Award, 1984. Forrest M. Bird Contributory Award, American Respiratory Therapy Foundation, 1985. Senior Executive Service Performance Award, 1985.

Authorship, Editorship: Author or Co-Author of 192 scientific publications Served on Editorial Boards of: Am. Journal of Physiology; Journal of Applied Physiology; Respiratory Physiology; Am. Review of Respiratory Disease; Undersea Biomedical Research; Proceedings of Society for Experimental Biology and Medicine; Revue Francaise des Maladies Respiratories; Journal of Applied Physiology; Respiration, Environmental and Exercise Physiology; Am. Journal Am. Journal of Medicine; Continuing Education for Family Physicians; Executive Editor of 38 volume monograph series, Lung Biology in Health and Disease.

FISCAL FLEXIBILITY

Senator WEICKER. I have somewhat the same question I had of Dr. Renault. To the extent that in the fiscal year 1986 Senate report, the committee directed NIH to disregard OMB's substantive directions on the use of apportioned funds, I want to remind the Institute directors that they retain their responsibility to adjust budget authority to take advantage of unanticipated research opportunities.

Do you feel you currently have sufficient flexibility to take advantage of unanticipated research opportunities?

Dr. LENFANT. Mr. Chairman, our budget for this year is broken down into a number of lines resulting from a very precise apportionment. As yet, we haven't requested any reprogramming.

As you know, the apportionment is given on the basis of the aggregate NIH and, in turn, Dr. Wyngaarden distributes a piece of it, if you will, to each of the Institutes. Thus, what I would ask, to change in one of my budget lines, would have to come from some other Institute's line, so that the total remains the same. I think that probably this is going to be a very difficult process to realize.

Again, in all fairness, I must say, as yet, we haven't made any specific request.

Senator WEICKER. I just want to make sure, in the fiscal year 1987 budget?

Dr. LENFANT. We don't have it, so we don't know as yet what is there. I guess it will be distributed or apportioned with the same degree of specificity as the 1986. My comments were in reference to 1986, and they applied to the end of 1985 as well, since in the last 2 months of the last fiscal year, we were given a very precise apportionment, which very much complicated things from our viewpoint.

Senator WEICKER. The minute you go outside those specifics then you have to do what?

Dr. LENFANT. We have to send a request to Dr. Wyngaarden, and it is my understanding that Dr. Wyngaarden has to send it up through the bureaucracy until eventually it comes to you.

Senator WEICKER. Is that correct?

Dr. WYNGAARDEN. We have reprogamming authority within certain parameters, beyond which we must submit a formal request for reprogramming to the Appropriations subcommittee; the request goes through PHS, the Department, and OMB on the way.

We have been able to do that, but it is a somewhat tortuous route. I think the Institutes aren't likely to request reprogramming authority until they really must do it.

Senator WEICKER. How did this come to pass, this system?

Dr. WYNGAARDEN. As far as I am aware, it has been this way during my 4 years as Director.

Senator WEICKER. You cannot shift from mechanism to mechanism.

Dr. WYNGAARDEN. No; not without getting permission if it exceeds a certain amount.

Dr. LENFANT. You may recall, Mr. Chairman, that at the end of last year, we had numerous discussions about the number of centers we could fund. One of the issues was related to the fact that we had a given, fixed, allocation for centers, and no flexibility to shift additional money in order to pay a new center as our National Advisory Council advised us to do.

AIDS FUNDING

Senator WEICKER. I understand that your Institute has a program of research focusing on the transmission of AIDS by blood transfusion, as you have indicated in your testimony. Have you had to reprogram funds from other areas, and has this reprogramming delayed other important research?

Dr. LENFANT. Since our AIDS Research Program began, we have committed $26.6 million to it, including $11 million in 1986. All of these moneys have been taken away from other activities such as our research program in sickle cell disease, or Cooley's anemia except for $1 million which we received by way of a special supplemental appropriation in 1984. However, the other $25.6 million which we have committed over the years all came from other activities. It was a deliberate decision because we thought and felt that our program would contribute to the AIDS research, but clearly, it meant that other things would not be done because of that reprogramming of funds.

Senator WEICKER. Was that your decision, or somebody else's decision?

Dr. LENFANT. It was our decision. However, at this point in time, for 1987, as you heard this morning, all the funds have been placed in the Office of the Assistant Secretary. Within this amount our share is $17 million. If these moneys would not come back to us, although I trust that they will come to us, but if they would not come to us, the Institute would be placed in a very precarious situation.

CLINICAL TRIALS

Senator WEICKER. What clinical trials do you have that are not going to be performed, if you could synopsize very briefly?

Dr. LENFANT. We have a number of clinical trials which have been proposed. One, for instance, is a comparison of the efficacy of coronary artery surgery with a technique that consists of inserting a catheter at the site of an occlusion of an artery, and at the tip of the catheter is a

balloon which you can inflate to break up the narrowing of the artery. So that is one, comparing these two techniques, and to what patients it would be best applied.

We have one on assessing the feasibility and efficacy of dietary intervention in children, in line with what Senator Proxmire was talking about.

We have another one to assess the efficacy of estrogen supplementation in postmenopausal women as the preventive regimen of coronary heart attack. As you may know, Senator, during the premenopausal period, the incidence of heart attack in women is far less than in men; however, past the menopausal period, then the incidence becomes higher and equal to that in man.

There are some indications that supplementation of estrogen might prevent that. It is a topic that is extremely important.

Senator WEICKER. Let me ask you this. How many clinical trials had you proposed, and how many are you going to conduct?

Dr. LENFANT. In 1987, we are going to initiate none, but we had proposed nine.

Senator WEICKER. Senator Proxmire.

COFFEE AND HEART DISEASE RISK

Senator PROXMIRE. Dr. Lenfant, a Johns Hopkins study, reported on last year, indicated that drinking five cups of coffee a day more than doubles the risk of heart disease. One of the researchers, Dr. Thomas A. Pearson, recommended that coffee drinkers interested in maintaining a prudent lifestyle cut back coffee consumption to no more than two cups a day. Do you believe that coffee consumption and heart disease are linked?

Dr. LENFANT. This is a very controversial subject. There are some conflicting views. When this study came from Johns Hopkins, a similar study came from Stanford but with different results. The interesting thing, let me say, is that it may not be related to caffeine. In fact, another study has demonstrated that there may be an increased risk of heart attack using decaffeinated coffee.

Senator PROXMIRE. Decaffeinated coffee has the same effect?

Dr. LENFANT. Yes; this being said, an excessive intake of caffeine is not to be recommended for the reason that it may cause some disorders of, or irregular heartbeats.

Senator PROXMIRE. Do you know why coffee increases the risk of heart disease, if caffeine isn't the reason?

Dr. LENFANT. No; there have been quite a few studies that are attempting to answer that question.

Senator PROXMIRE. It seems to me that the answer is very important because people throughout the world consume enormous quantities of coffee. It might be a contribution to better health if we could cut that consumption down, since the Hopkins study says that coffee doubles the incidence of heart disease.

Last year, you told us that a comprehensive trial to determine the extent to which hypertension can be controlled through changes in lifestyle—diet and exercise, for example—was listed for 1986. Has this trial been initiated and, if so, when can we expect preliminary results?

Dr. LENFANT. It has been initiated. It will take 4 or 5 years before it is completed. It is a very complex study, yet a most important one.

Senator PROXMIRE. Thank you very much.

PROGRAM BALANCE

Senator WEICKER. Let me ask you a question that I asked of Dr. Wyngaarden, so that I can have a second opinion.

Do you feel that in my focus on the grants, I may have been neglecting the other aspects of the Institutes, research training, intramural research, et cetera?

Dr. LENFANT. There is no question that we have reached a very critical point, and let me give you two sets of figures. In 1980, our Institute was devoting 58 percent of its resources for research grants, almost 14 percent for our center programs, 17.3 percent for our clinical trials. Today, in 1986, the figures are 70.4 percent in research grants, which is an increase of approximately 12 percent due to shifted resources from other mechanisms to the research grants; the research center program has gone down to 10 percent, which is a loss of 4 percent. In the clinical trials, our current allocation is only 7 percent for this year, which is a considerable decrease.

Senator WEICKER. I like those figures, and I would like to have the same figures for other Institutes.

Dr. LENFANT. We are a clinical institute, and we are dealing with a large number of clinical problems. The reason why our National Advisory Council has encouraged us to diversify our mechanisms of support is so that we would be able to approach the problems facing our Institute, particularly to be able to support a fairly large amount of clinical research.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Thank you very much for your response. Also, there will be further questions for response to the record. I would like to be able to spend more time with you, but unfortunately I have to close this thing by 1 o'clock, and I have two more Institutes to go.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

AIDS - BLOOD TRANSFUSIONS

Question. I understand that your Institute has a program of research focusing on the transmission of AIDS by blood transfusion. Can you briefly describe what you are doing?

Answer. More than 18,000 cases of acquired immunodeficiency syndrome (AIDS) have been reported in the United States as of the beginning of March 1986; 1 percent of adult cases occurred in hemophiliacs, and 2 percent are transfusion related.

The National Heart, Lung, and Blood Institute (NHLBI) supports a major, multicenter project on immunologic changes that occur following blood transfusion and the possible association of these changes with the development of AIDS. This study will enroll transfusion recipients and donors of blood collected from healthy donors before HTLV-III antibody tests were available but who are now known to have HTLV-III antibodies. Another major aspect of this study will be to evaluate immunologic impairment and HTLV-III infection in people who receive blood transfusions or blood products regularly because they have hemophilia, sickle cell disease or Cooley's anemia. The study will attempt to answer important questions regarding the transmission of HTLV-III by blood transfusion and the effect of other diseases upon expression of the virus.

As part of its mandate to support research to improve the safety of the blood supply, the Institute fosters development of blood tests, methods to inactivate infectious agents, and development of globulin fractions to block infection. The NHLBI is in the second year of a program to develop tests for AIDS carriers and has just released a request for proposals for development of more specific blood tests. An ELISA test using a chemically synthesized peptide, identical to part of the envelope of HTLV-III, is under development and may lead to a more specific assay than current tests for antibody to HTLV-III. This same peptide may also be useful as a vaccine since it elicited antibodies to the virus in rabbits and in a chimpanzee. A promising method to inactivate HTLV-III in blood products which has potential application in the preparation of safe, effective blood derivatives has been developed under research contract. The Institute also supports a contract to develop an immune globulin which may provide passive immunization to people who have been exposed to the AIDS virus.

Appropriate animal models for AIDS are indispensable for understanding the clinical course of the disease, for determining safety and efficacy of therapeutic agents, and for confirming viral inactivation in blood products. The Institute supported the first study establishing the chimpanzee as an animal model for HTLV-III infection. The investigators on this project have recently succeeded in transmitting the virus from chimpanzee to chimpanzee and are currently examining factors that may contribute to the progression of HTLV-III infection from the asymptomatic state to overt AIDS.

Question. Have you been able to fund this research from the funds appropriated to the Director's office?

Answer. Funding for AIDS research in FY 1986 has been provided from the NHLBI appropriation. To date, the Institute has not been allocated any additional money for AIDS from the appropriation of the Office of the Director, NIH.

Question. Have you had to reprogram funds from other areas?

Answer. From FY 1983 to FY 1986 the National Heart, Lung and Blood Institute has provided $26,114,000 for AIDS research. This was during a period of increasing appropriations for the Institute. AIDS projects competed in priority for these funds.

Question. Has this reprogramming delayed other important research?

Answer. Yes, but shifts from lower-priority areas to higher-priority areas occur constantly.

AIDS - BLOOD TEST

Question. I understand that research on developing a better blood test for AIDS is proceeding well. Can you bring us up-to-date on expected results of this research?

Answer. In 1984, NHLBI issued a request for applications (RFA) to support research on tests for AIDS carriers. The NHLBI recently released a request for proposals (RFP) encouraging research and development for more sensitive and specific tests of exposure to or infection with HTLV-III. This program will include research to develop more specific antibody tests to serve as confirmatory procedures for current assays and to devise blood screening tests that detect the virus or its components, whether free, inside cells, or circulating in the blood as virus-antibody complexes.

The research results from the current RFA program show exciting promise. Commercial assays to detect antibody to the AIDS virus contain partially purified, disrupted virus as a source of viral antigen and some contaminants from the cell line in which the virus was grown; these contaminants can cause non-specific, or false-positive, reactions. Contamination can be avoided by chemically synthesizing a piece of the outer coat of HTLV-III; such a peptide has been prepared by NHLBI-supported investigators. ELISA tests using such a synthetic peptide should be more specific than currently available procedures and potentially reduce or eliminate the need for expensive confirmatory tests, such as the Western blot. Another developmental assay system utilizes monoclonal antibodies to HTLV-III components. These antibodies will be used in a "sandwich" immunoassay which is expected to permit the specific identification of HTLV-III components produced at various stages of viral infection. In another approach, nucleic acid hybridization methods are being used to detect as few as 10,000 virus particles, the approximate number of virus particles in one infected cell.

Question. If this new test proves promising, will you have enough funds in the FY 1987 proposed budget to complete the necessary research?

Answer. The Institute released an RFP for development and evaluation of new screening tests for HTLV-III antigens, antibodies or nucleic acid in February 1986. Any tests developed under the RFA previously discussed could be evaluated for sensitivity and specificity under contract in response to this RFP. The NHLBI plans to fully support this program for test development and evaluation in in FY 1987.

Question. How much more would be necessary?

Answer. As currently planned, no additional funds would be necessary.

AIDS - REPROGRAMMING PROBLEMS

Question. How much money will your Institute receive specifically earmarked for AIDS research in FY 1986?

Answer. Under the revised budget request, NHLBI has earmarked $10.7 million for AIDS.

Question. How much money will you spend on AIDS research in FY 1986?

Answer. In FY 1986, we plan to spend $10,718,000 on AIDS research.

Question. How much of this money had to be taken or reprogrammed from other activities, functions or programs?

Answer. The changing nature of science demands that existing allocations of resources be continually re-assessed to ensure that high-priority areas receive sufficient support. Given that AIDS is the Department's highest priority we naturally redirect funds from lower-priority areas to AIDS research.

Question. For the record, please list all activities, functions or programs that were raided for this purpose and describe the specific impact on each.

Answer. No raids occured. Instead, in the normal allocation and reallocation process AIDS was deemed to be a higher priority than certain other areas. In a sense, every NHLBI activity is affected by the decision to fund AIDS at adequate levels, for in the absence of the public health threat of AIDS, it is likely that these additional funds would be used to augument research into lower-priority areas.

Question. Please provide the committee the same information for personnel changes caused by an FTE shortage in the areas of AIDS-related research.

Answer. Since Institute funding for AIDS research is provided through the extramural program, the program has affected extramural staff requirements. No FTE's have been provided. Therefore, the Institute has initiated several time-saving, effort-reducing methods in order to keep pace with the complex management issues that have emerged with the rapidly expanding AIDS program. This task is difficult because of the cross cut-

ting issues and rapidly emerging research results that have occurred.

LOST RESEARCH INITIATIVES

Question. On January 29th of this year one of your Scientific Advisory Council's published 11 research initiatives in the areas of arteriosclerosis and hypertension (list attached). Why were these initiatives chosen as important research to be supported?

Answer. The initiatives referred to are the result of year long planning by the Institute's Arteriosclerosis, Hypertension and Lipid Metabolism Advisory Committee working with the scientific staff of that program area. The importance of each of these initiatives is described below:

Health and Nutrition Examination Survey (HANES) III 1987-1994

The National Center for Health Statistics (NCHS) conducts periodic surveys of the health and nutritional status of the U.S. population. The surveys to date have all included determinations of blood lipids, especially cholesterol. These lipid values are extremely important for monitoring national trends in both the majority and minority populations and help in interpreting the decline in coronary heart disease mortality observed in the United States since 1968. Monitoring of cholesterol levels will be of additional value in relation to the National Cholesterol Education Program (NCEP). Recent studies suggest that mean plasma cholesterol levels have dropped in the U.S. population over the past 10 years. Planning is currently under way for HANES III. This much larger survey will extend over a period of 6 years and will be a nationally representative sample of children and adults. It will include blacks and Hispanics, as well as low income, preschool and elderly populations. To insure comparability of these measurements over a period of many years, it is essential that the HANES lipid measurements are of the highest quality with respect to their precision and accuracy. Accordingly, NHLBI will continue to assume responsibility for the performance of these measurements.

Research on Hypertension in Pregnancy

Up to 26 percent of all pregnancies are complicated by hypertension, causing the death of 10 to 25 thousand infants each year together with a significant number of mothers. Also hypertension is the single most frequent cause of premature births, resulting in thousands of hospital days, especially in neonatal intensive care units. Such a serious public health problem prompts this joint initiative between the NHLBI and the National Institute Child Health Development (NICHD), in seeking to increase the number of scientific investigators in an area where few are now engaged, where no animal models of the condition are available, and where adequate resources for research currently do not exist.

Workshop on Interaction of Hypertension and Lipoprotein Metabolism

There are many links between the levels of blood pressure and of the various plasma lipids (fats in the blood), such as cholesterol. Elevations in both contribute to vascular disease in general, and coronary heart disease in particular. But the extent to which these links are underpinned by common mechanisms is not known. Also, certain forms of drug therapy for hypertension appear to produce unwanted changes in plasma lipids. This workshop is timely in that it will bring together investigators from two related, but usually separate disciplines--hypertension and lipoprotein metabolism--to carefully examine the possible interrelationships involved, and to recommend future directions for research on an important clinical problem, that of coronary heart disease.

Hypertriglyceridemia, Atherosclerosis and Thrombosis

There is evidence that hypertriglyceridemia is associated with hypercoagulability, and that certain abnormal subclasses of triglyceride-rich lipoproteins are potentially highly atherogenic. Also, several reports indicate that elevated plasma triglyceride levels are a risk factor for myocardial infarction. Myocardial infarction is a result of thrombosis in atherosclerotic coronary arteries, and the thrombotic process may play an important role in initiating or aggravating atherogenesis per se. This thrombosis may be a means by which hypertriglyceridemia increases coronary heart disease risk.

Feasibility Study for a Clinical Trial of Postmenopausal Estrogen Use and Coronary Heart Disease Risk (CHD)

The life expectancy of American women is 78 years. More than one-third of those years are postmenopausal. Heart disease is the second leading cause of death in women ages 40-64; it is the leading cause of death thereafter.

Several prospective and other types of epidemiological studies have suggested that postmenopausal estrogen replacement therapy is associated with a marked reduction in the death rate from cardiovascular disease. The need for further study of these relationships is heightened by evidence that use of postmenopausal estrogen is increasing. Some of the progestin agents currently used in combination with estrogen may counteract the purported beneficial effects of the latter. Studies are required to identify estrogen-progestin combinations with potentially desirable effects on cardiovascular risk factors.

Effects of Dietary Factors on Lipoprotein Structure and Metabolism

Elevated blood cholesterol is a major cause of coronary artery disease. The cholesterol levels of average Americans put them at increased risk for developing heart disease compared with populations with lower cholesterol levels. High blood cholesterol levels can be reduced by diets that are low in saturated fat and cholesterol. Further reductions are often attainable with addition of water soluble gel-forming fibers. Recent advances in

basic research have led to increased understanding of the metabolism of lipoproteins and their subfractions and their role in atherogenesis. Currently little is known as to how diet affects these processes.

Mechanism of Obesity-Associated Hypertension

Obesity-associated hypertension is a serious health problem affecting an estimated 25 million Americans. It is difficult to control because weight reduction in obese persons is difficult to achieve and maintain. A more rational long term strategy is to prevent the condition. Thus this research initiative encourages scientists to seek the underlying genetic and other molecular mechanisms responsible for obesity-associated hypertension. Only in that way can the condition be sufficiently understood so that preventive strategies can be devised.

Are Americans Changing Their Diets? Methodological Issues

Over the past decade Americans have been advised to follow a set of prudent dietary goals and guidelines in the selection of food in order to promote optimal health and to reduce the risk of chronic diseases such as heart disease. Evidence of clear trends in food consumption that are consistent with those goals, such as reducing the intake of saturated fat and increasing the intake of fiber, is difficult to document with existing large survey data bases, although specialized surveys suggest that changes have taken place among some segments of the population. The National Cholesterol Education Program (NCEP) is expected to increase public awareness of the need for making prudent dietary changes. If the effectiveness of this campaign on food habits is to be measured, adequate baseline information is needed as well as more sensitive methods for monitoring change.

Coordinating Center for NHLBI Renovascular Hypertension Registry

Renovascular hypertension, caused by narrowing of the main artery to a kidney, is responsible for kidney disease, high blood pressure and kidney failure, in as many as one million Americans. There is no widely accepted diagnostic strategy and the choice of treatment is controversial. This initiative would encourage the pooling of data according to a standardized protocol to determine whether dilation with a balloon catheter (angioplasty) is efficacious, safe and cost-effective in the treatment of renovascular hypertension. The proposed registry will be much less costly than a full-scale clinical trial, yet will provide useful information.

Plasma Lipoprotein Response to Dietary Fat and Carbohydrate Modification in Moderate-Risk Hypercholesterolemia

The Consensus Development Conference on Lowering Blood Cholesterol to Prevent Heart Disease reached the conclusion that adults with moderate-risk blood cholesterol levels (as well as those at higher risk) be treated intensively by dietary means. These constitute about 15 percent of the U.S. population. Most persons in the moderate-risk category are expected to respond to diet

alone. At present there is limited information on the effect of diet in men and women in the moderate-risk group since most intervention studies have concentrated on men in the high-risk category. Several dietary therapeutic options (all reduced in saturated fat and cholesterol) exist. Further evaluation is necessary to determine the most efficacious dietary regimens in terms of plasma cholesterol lowering and absence of potentially harmful side effects.

Long Term Efficacy of Anti-Hypertensive Drug Treatment--
Experimental Evaluation of Individual Agents

Although lowering blood pressure with anti-hypertensive drugs decreases cardiovascular disease mortality, it is not known which specific drugs impact on which specific cardiovascular disease. Seeking such knowledge from studies on humans would require considerable expenditure of time and money. This initiative, employing animal models of hypertension, in which the lifetimes of the animals do not exceed 2 years, and employing typical antihypertensive drugs, would provide necessary information on this subject in a timely fashion, and in a way not otherwise available.

Question. Given your proposed budget is $62 million less than the FY 1986 appropriated budget, how many of these initiatives will be pursued?

Answer. Although we will be able to place emphasis on a number of these important areas of research, we have not decided exactly which ones will be fully pursued in FY 1987.

RESEARCH PROJECT GRANT

Question. I note from your budget justifications that you propose reduction of 84 new grants for FY 87. What kind of research will be delayed or lost by this reduction?

Answer. The FY 87 budget proposed to fund 2,605 total grants, a 4% reduction from the 1986 level of 2,704. This slight decrease will modestly affect a number of research areas, but given the nature of the peer review process and the ever-changing priorities of the Institute, it is impossible at this time to identify precisely which particular areas will be modestly affected.

Question. Please give us an example of the long range impact of this kind of loss or delay.

Answer. There would be a very slight delay in the acquisition of knowledge that could lead to the betterment of American health through prevention and improved health care.

ARTIFICIAL HEART

Question. I understand that research on the artificial heart has focused mostly on the development of the mechanical device. Recognizing the concerns about long-term use of this device, what are your plans for further research?

Answer. The immediate goal of the mechanical circulatory support program is validation of an electrically powered implantable

ventricular assist system with a 2-year reliability. The purpose of this program is to conduct laboratory and animal tests to evaluate the suitability of these devices for clinical investigation in patients, tentatively scheduled to begin in FY 1988. In parallel with these ongoing device tests we are fostering the development of guidelines, using nonfederal consultants, for future patient selection, clinical procedures and patient management in light of present clinical experiene. Clinical research will not be initiated until we are sure we have safe and effective devices and the necessary methods to study the interactions of these devices with the patient. This stepwise approach was successfully employed in establishing the clinical usefulness of other devices such as the intra-aortic balloon and air-driven short-term ventricular assist devices. The Institute's future plans include a program for research and development of miniature implantable biventricular assist and replacement devices that will have improved capabilities based on the results of the past decade of laboratory, animal, and clinical research.

Question. Why are the recipients of the artificial heart susceptible to stroke?

Answer. The recipients of the artificial heart device are susceptible to stroke because any foreign surface in contact with blood tends to promote the deposition of fibrin and other blood constituents to form a clot or thrombus, which can then be broken off by the blood streaming by and carried in the arterial system until it blocks off an artery. If it lands in the brain, the result is a stroke. A second factor is the potential for hemorrhage in the brain due to medications given to decrease the propensity for blood clot formation and possibly due to modification in the clotting factors in the blood due to the device. The factors that are involved are very complex and the Institute is supporting basic and applied research on the biomaterials used in mechanical devices to control or prevent these phenomena. Specifically, studies are focused on minimizing the interaction of blood and materials so that blood clotting capabilities are neither activated nor eliminated. Thus even when future devices are implanted, hemostasis will remain within the normal range. The current implantable ventricular assist systems completing development and validation testing have a controlled pumping action which lowers the stress and strain on the biological layer which forms on the lining of the blood pumping chamber, the valves, and inflow and outflow conduits. This controlled pumping action, in contrast to the random collapse pattern of current air-driven artificial hearts, is likely to lower the occurrence of blood clots which can lead to brain embolism and stroke.

Question. Is it true that the natural heart may also be producing a hormone that controls central blood pressure?

Answer. It is true that the natural heart has a hormone called atrial natriuretic factor that plays a role in sodium excretion and blood pressure regulation. However, little is known about the availability or functional capabilities of this hormone in patients with end-stage heart disease who might be candidates for mechanical circulatory support devices. Presently, surgical implant procedures for devices only minimally involve the atrium which is the source of the hormone. For an artificial heart the diseased

ventricles are removed and the prosthetic ventricles are sutured to the atrial remnants. For a ventricular assist device, the patient's heart remains in place. Future research on mechanical circulatory support will need to address the role of residual hormone and its influence on blood volume and blood pressure.

CHOLESTEROL

Question. Last year you discussed the initiation of a National Cholesterol Education Program which would be like your successful high blood pressure education program. Can you describe what this program will accomplish and tell us what has happened thus far?

Answer. The purpose of the National Cholesterol Education Program (NCEP) is to help prevent coronary heart disease by reducing elevated levels of blood cholesterol in the United States. The NCEP will seek to accomplish this purpose through a national educational effort aimed at the public and health professionals to increase their awareness of the importance of lowering elevated blood cholesterol levels, encourage them to take action, and improve their knowledge and skills with which to do so.

Like the successful National High Blood Pressure Education Program (NHBPEP) on which it is modeled, the NCEP will build on two principles: it will base its educational messages on a strong and continually developing foundation of current scientific findings; and it will establish an extensive network of partnerships and cooperative arrangements with private sector organizations, including industry, and with other government agencies in order to mobilize a wide range of resources and exert a coordinated nationwide effect on this important health problem.

The NCEP plans to target its messages and materials to four audiences or areas: the public; health professionals; the worksite, to foster the adoption of cholesterol lowering programs at the place of work; and schools, to encourage the introduction of cholesterol-related information into the curriculum to increase students' understanding of the importance of blood cholesterol as a risk factor for heart disease. Ultimately, the educational efforts of the NCEP may be expected to produce benefits similar to those of the NHBPEP: a better informed public, and a better educated and motivated health profession, leading to improved detection, evaluation, and treatment of one of the Nation's most serious health problems.

The NCEP is off to a promising start. The program has established its Coordinating Committee, comprised of representatives of over 20 health and medically related organizations and eight Federal agencies, to focus the energies of all the groups participating in the national effort. The first meeting of the Coordinating Committee, which took place on November 15, 1985, marked the official launching of the NCEP, and the committee has since met a second time. The initial wave of messages for professionals and the public has been produced and is being distributed. A new booklet titled Cholesterol Counts, to provide practical advice to health professionals on the management of high blood cholesterol, is currently being sent to the membership of the health professional associations, starting with those on the Coordinating Committee. The NCEP's first public service announcement has been completed, conveying to the public the message that they should know their own

blood cholesterol levels. This announcement has been distributed to the networks and television stations in the 20 largest TV markets in the United States and should begin to appear on the air by late March. "A Fact Sheet on Blood Cholesterol" is being distributed to the public in a variety of settings and is being sent out in response to public inquiries. A public inquiry response center has been set up, and is currently responding to about 700 inquiries a month. This volume is expected to increase after the appearance of the first TV spot.

In addition, several important projects have been begun. Two expert panels have been established: one to develop clear and authoritative guidelines for health professionals on the detection, evaluation, and treatment of high blood cholesterol in adults; and the other to foster improved standardization in the way laboratories conduct and report cholesterol determinations. These panels will be working over the next year's time. A continuing medical education curriculum is under development in order to provide the right framework in which health professionals can learn the principles of cholesterol management. Materials and messages for the worksite are being developed.

Finally, cooperative efforts with industry have been started, in particular in the area of providing educational messages to professionals. The net effect of all these activities appears to be an increasing level of interest in the issue of cholesterol, as evidenced by increasing attention on the part of the public, the lay press, professional journals, and business.

Question. Are you requesting enough funds to support this program at its planned level of effort? If not--how much more funding would be necessary?

Answer. The National Cholesterol Education Program (NCEP) draws on a variety of sources of support both within the NHLBI and outside it. As mentioned in the previous answer, the NCEP will seek to involve a wide range of outside organizations in carrying out the national educational effort. The resources contributed by those organizations, including voluntary and professional agencies and industry, are critical to the success of the program, since the job is bigger than can be accomplished by any one entity.

ESTROGEN THERAPY AND POST-MENOPAUSAL WOMEN

Question. I have heard that a controversy exists over the use of estrogen therapy in post-menopausal women. Can you clarify this controversy for the Committee--especially in the area of cardiovascular disease?

Answer. The controversy is whether post-menopausal estrogen use decreases or increases the risk of cardiovascular disease morbidity and mortality. A number of studies including the Lipid Research Clinics Follow-up Study and most recently, the Nurses' Health Study have reported that post-menopausal estrogen users experience between one-third to one-half the mortality and morbidity of non-users. Data from the Framingham Study, on the other hand, suggest that compared to non-users, post-menopausal estrogen users have more than a 50 percent increased risk of

cardiovascular disease morbidity and more than twice the risk for stroke. Framingham results do not suggest any difference between the two groups in total and cardiovascular mortality. The explanation for these differences is not clear.

Question. What research are you doing and should you be doing to provide answers to this controversy, and how much will that research cost?

Answer. Further analyses of data from Framingham, the Lipid Research Clinics Program, and the Nurses Health Study will continue. There has been some indication that, when the Framingham data are analyzed using comparable age groups and definitions for cardiovascular disease as those used in the other two studies, beneficial results are observed.

Representatives from the NHLBI as well as from the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institute of Child Health and Human Development, National Institute on Aging, and the National Cancer Institute have been meeting over the past few months to discuss joint avenues of research in this area. It is likely that this group will recommend a research plan that will evaluate estrogen/progestin combination therapies in terms of beneficial effects on cardiovascular risk factors, osteoporosis and other measures.

UNDERSEA, AEROSPACE AND HYPERBARIC MEDICAL ACTIVITIES

Question. The National Institutes of Health has many research centers dedicated to the study of specific diseases. It does not, however, have a center for the study of healthy human beings living in stressful environments such as outer space and the deep oceans. Considering the importance of these frontiers to our future, the committee last year provided the Heart, Lung, and Blood Institute with $400,000 to establish and provide core support for a National Center to serve as a focus for research advancing undersea, aerospace and hyperbaric medical activities. It is my understanding that the Institute has put out a request for applications (RFA) for this grant. When do you expect to identify this National Center and are these funds to be granted in one year as directed?

Answer. In response to the Committee's directive, the Institute issued an RFA in December 1985 for a single competition for core support of laboratories with existing facilities for hypobaric and hyperbaric research in humans and/or vertebrate animals. Applications which are successful are expected to be awarded for up to a 2-year period beginning September 30, 1986. The Institute will award these core facilities as regular research grants instead of center grants because the intent of the program would not fall within the guidelines of our current centers program; the Specialized Centers of Research Program requires both basic and clinical research focused on a specific heart, lung or blood disease.

We are satisfied that provisions of support for these core laboratories through the regular research grant mechanism will meet the Committee's intent. We look forward to working with successful applicants to incorporate this core support into

research project grants with objectives related to the NHLBI mission.

Question. Can you assure me that the Institute will continue to recognize and support this Center as a long-term need?

Answer. The Institute plans to provide 2 years of support, not to exceed a total of $400,000 per year, for applications that are awarded in response to the Committee's request. These awards will be in addition to the core support that is provided in awards that are already made by the Institute in this research area, including both program grants and regular research grants that have been submitted through the traditional NIH system. The Institute has had a long-term commitment to provide research and core support for both hypobaric and hyperbaric research through our grant program. We expect to continue to provide support for as many highly meritorious projects as possible in the future.

The major focus of the Institute in this area has been toward understanding physiological responses of the cardiovascular and respiratory systems at both simulated altitude and depth. Studies of healthy human beings living in stressful environments such as outer space and the deep oceans has never been considered a mission of the NHLBI given the major responsibilities of the National Aeronautics and Space Administration, the National Oceanographic and Atmospheric Administration and the Department of the Navy in these areas.

FISH OILS

Question. I am encouraged by the plans of the NIH and National Oceanic and Atmospheric Administration (NOAA) to coordinate research efforts on the health effects of omega-3 polyunsaturated fatty acids contained in fish oils. One of the main objectives of the joint conference sponsored by NIH, NOAA, and the National Fisheries Institute last June was to establish a research agenda within NIH to examine this issue. Information presented at the conference indicated that omega-3 fatty acids play a potential role in the prevention and treatment of a number of diseases, including cardiovascular diseases and cancer. What is the nature and status of the National Heart, Lung, and Blood Institute's involvement in omega-3 research, specifically as it relates to fish oils?

Answer. In FY 1985 the NHLBI obligated about $900,000 for omega-3 fatty acid research in the areas of coronary heart diseases, thrombotic diseases and pulmonary diseases. Recently a substantial increase in investigator-initiated grant applications has occurred as anticipated. Two of the three projects on omega-3 reviewed at the February National Heart, Lung, and Blood Advisory Council had high merit and will be funded. An additional eleven projects are pending May 1986 Council review.

Additional research initiatives in omega-3 fatty acids have been developed within the past few months. A new research solicitation under consideration in the Institute's research plan for fiscal year 1987 is: Omega-3 Fatty Acids Mechanisms of Thrombogenesis and Blood Vessel Atherogenesis. This research initiative is specifically directed to research areas that are considered to

have the greatest potential significance for coronary heart disease and thrombotic diseases.

COST EFFECTIVE TREATMENT

Question. What research or studies does the Institute support that examine the efficacy and cost effectiveness of the various treatment and prevention modalities for heart and lung diseases?

Answer. The primary thrust of our assessment of therapies is for their clinical effectiveness and short-comings. However, we have also looked at the economic consequences of some of our major studies.

The Coronary Artery Surgery Study identified a class of patients with symptomatically mild coronary artery disease for whom bypass surgery was being performed frequently but who don't need surgery. The study showed that the strategy of medical management unless symptoms later dictate surgery results in the same excellent survival in this group as prompt surgery. The savings in direct hospital costs alone due to these results can reasonably be expected to approach $500 million per year--and many patients are relieved of the need for surgery.

An asthma self-management program was developed that consists of teaching children and families to comply with physician advice, take medications, avoid precipitants of asthma attacks, handle attacks, know when medical attention is needed, and cope with having a chronic disease that may severely limit their activity. In one study of the effect of this program in a health maintenance organization, patients enrolled in the education program had a dramatic reduction in the number of emergency treatments for asthma (average 1.9 visits) compared with the control group (average 7.4 visits) even though both groups had similar numbers of emergency treatments for asthma in the year preceding the education program. The saving to the health maintenance organization exceeded $500 per child per year for participants--and most importantly, the children and their families had less problems and stresses.

A new method has been developed for preparing blood for transfusion to patients with Cooley's Anemia and other conditions that require life-long transfusion therapy and need "washed" red cells, which are less antigenic. The new technique results in red cells that are substantially less damaged in processing than by the previous techniques. Thus, each transfusion lasts 50 percent longer and patients require one-third fewer transfusions. Also, because the new process is less expensive than the old, there are additional cost savings which amount to $2,600 per patient per year.

It must again be emphasized that we focus upon potential clinical benefits and fundamental scientific questions. It would be a mistake to conclude that each and every piece of our research leads to costs savings. However, all of our research goes toward improved biomedical and scientific knowledge, which is the foundation of improved care and better prevention. On the whole, these are cost saving and most importantly, they improve both the quantity and the quality of lives.

CENTERS

Question. I see that you are still planning to support 60 research centers in FY 1987 but at a reduction in funding of over $10 million from FY 1986 appropriated levels. Can these centers absorb costs of this magnitude without compromising their research efforts?

Answer. The centers involve all facets of fundamental biomedical science and each has major clinical programs. Some also have important demonstration and educational activities. Some projects will be delayed, limited in scope, or in some cases indefinitely deferred.

Question. If you fund an unanticipated research opportunity in one or more of these centers, do you have the flexibility to provide the additional funding necessary to exploit these new opportunities?

Answer. Any changes to the amounts shown in the budget require the approval of the Director of the National Institutes of Health (NIH). Depending on the nature of these changes, approvals may also be required from the Director, NIH; the Assistant Secretary for Health DHHS; the Assistant Secretary for Management and Budget, DHHS; the Office of Management and Budget; and the Chairman of the House and Senate Appropriations Committees.

MANAGEMENT FLEXIBILITY

Question. On page 57 of the FY 1986 Senate Report, the Committee directed NIH to "disregard OMB substantive directions on the use of apportioned funds" and went on to remind the Institute Directors that they retain the responsibility to adjust budget authority to take advantage of unanticipated research opportunities. Dr. Lenfant, can you tell us how this directive has been useful to you in setting your priorities for research centers?

Answer. The Office of Management and Budget (OMB) does not issue substantive directions on the use of apportioned funds, so that the directive has had little impact on NHLBI priorities. In setting priorities for research centers, I have tried to accommodate the expressed desires of the Senate Committee.

Question. Has this directive afforded an additional flexibility in responding to 4.3 percent sequestration of FY 1986 funds?

Answer. As stated above, the directive has had little impact.

FISCAL FLEXIBILITY

Question. I understand that lack of flexibility in the management of an Institute such as yours can be detrimental to both the research program and the research scientist. Can you describe the kind of flexibility you now have?

Answer. Our appropriation is divided into several cost categories. Within these cost categories, the Institute Director and Institute staff can decide which approved grants are funded, which research contract programs are funded and so forth. Some of

these cost categories such as heart and vascular diseases, lung diseases, and blood diseases and resources, intramural research, and research management and support, have been used as parameters and have controlled our actions for several years.

Based on discussions within NIH, NHLBI develops and periodically updates a financial plan describing our activities. Depending on the magnitude of the update, whether to take advantage of scientific opportunities or to facilitate the management of a program, the approval of the Director, National Institutes of Health (NIH), the Assisant Secretary for Health, DHHS; the Assistant Secretary for Management and Budget, DHHS; the Office of Management and Budget; and the Chairmen of the House and Senate Appropriations Committees may be required.

Question. Please give us examples of where additional flexibility would be necessary to achieve better management of your scientific responsibilities.

Answer. There are several areas where additional flexibility would be necessary to achieve better management of scientific opportunities. For example, each year some of our 11 distinct centers programs may recompete for additional funding. At the time the budget is put together, it is not known whether some of the applications will propose high quality research that may cost somewhat more than the amount for competing research centers in the budget. Prudent management may dictate that the Institute Director move a small amount of funds to competing research centers from noncompeting research centers, because, for example, unanticipated savings in ongoing centers have become available. Prior to FY 1986, the Institute Director could make these changes without higher level approval. Now, the Institute Director may need to seek, the approval of the Director, NIH.

Question. How has Gramm-Rudman-Hollings sequestration affected your management flexibility?

Answer. The Gramm-Rudman-Hollings sequestration legislation applies across the board reductions to each program, project, or activity. Across the board reductions sometimes create inequities or management problems that could be resolved if greater flexibility existed.

IMPACT OF BUDGET REDUCTION

Question. The President's budget proposal for FY 1987 reduces your budget by $62,342,000 under FY 1986 appropriated levels. Gramm-Rudman-Hollings, if triggered, could reduce your budget even further--maybe by as much at 20 percent. I've known this would reduce the number of grants, possibly the size of grants, centers, training, etc. Can you give us some idea of the impact of these reductions on the kinds of research that would be stopped or lost?

Answer. Since the 1987 President's Budget was developed to comply with the deficit reductions targets established in Gramm-Rudman-Hollings, it is unlikely that a further reduction of this magnitude would occur. If reduction of this magnitude were to occur, the Institute would probably have to eliminate certain major population studies and clinical trials; reduce the numbers of

centers; and reduce its research project grant awards substantially. It is not possible to say precisely what research would be lost.

Question. What impact might this have on the health of our citizens five and ten years down the road?

Answer. It is not possible to assess the impact of such reductions on the health of the American people. My professional judgment, based on past research achievements, is that the health impact would be unfavorable.

Question. Can you discuss your contingency plans if these massive budget cuts should come to pass?

Answer. The Institute is not developing such contingency plans at the present time. Contingency plans of this nature would be developed only if it becomes clear that reductions of this magnitude would occur.

CLINICAL TRIALS AND POPULATION-BASED STUDIES

Question. This Subcommittee has supported population-based studies and clinical trials of new therapies with the understanding that these trials and studies provide important epidemiologic information to the practicing physician. Can your Institute continue to support these studies given the FY 1987 budget proposal?

Answer. The Institute considers clinical trials and population-based studies to be very important. Those trials which are now ongoing will be able to continue with the FY 1987 budget proposal but we have had to modify the pace of patient recruitment and delay the ultimate completion of the trial.

STUDIES NOT SUPPORTED

Question. Can you provide this Committee with a list of the types of studies that will not be supported in FY 1987 and give us the impact of this lack of support on the health if our population?

Answer. The FY 1987 budget proposes to fund 2,605 total research project grants, a 4 percent reduction from the 1986 level of 2,704. This slight decrease will modestly affect a number of research areas, but given the nature of the peer review process and the ever-changing priorities of the Institutes, it is impossible at this time to identify precisely which particular areas will be modestly affected.

Nine clinical trials to test new therapies are being deferred. These include: Bypass Angioplasty Revascularization Investigation (BARI--a comparison of percutaneous transluminal coronary angioplasty and coronary artery bypass graft surgery for the management of patients with severe angina pectoris); dietary intervention in children with elevated low density lipoprotein levels; treatment of pulmonary embolism with thrombolytic agents; continuous positive airway pressure for treatment of sleep apnea; penicillin prophylaxis in sickle cell disease; natural history of posttransfusion non-A non-B hepatitis; deep vein thrombosis diagnosis and treatment; post

coronary artery bypass graft program; postmenopausal estrogen use and coronary heart disease risk.

Because research centers are significantly reduced in FY 1987, it is likely that individual projects within these center programs will be deferred or dropped completely. Deferral or elimination of projects is more likely to occur among the 24 centers that are competing for renewal in FY 1987. Therefore, projects in arteriosclerosis, pediatric pulmonary disease, chronic obstructive pulmonary disease, occupational and immunological lung diseases, and pulmonary vascular diseases may be deferred.

A number of initiatives in addition to the clinical trials will have to be deferred including: omega-3 fatty acids and reduction of the incidence of thrombosis and coronary heart disease; effects of dietary fat on lipoprotein structure and metabolism; hypertension in pregnancy--population at risk and treatment; mechanism of obesity associated hypertension; laser applications in cardiovascular treatment; minimally invasive techniques to detect coronary artery lesions; narrowing and occlusion of natural and synthetic grafts; coronary heart disease and stroke in the elderly; health care seeking experience among blacks for coronary heart disease; congenital heart, lung, and blood malformations program; and development of hemostatic mechanisms in the newborn.

The intramural research studies to be affected include chemical and pharmacological research; research on experimental atherosclerosis; clinical hypertension; heart rhythm problems; abnormal plasma lipoproteins; preclinical and potential clinical trials of gene replacement therapy for certain genetic diseases; development of novel therapeutic approaches for treating pulmonary emphysema; development and clinical testing of prosthetic heart valves; and clinical evaluation of the results of coronary bypass surgery.

IMPACT OF FURTHER SEQUESTERING IN FY 1987

Question. If the automatic provisions of Gramm-Rudman-Hollings are triggered in FY 1987, your Institute may well have its budget reduced by 20-25%. Have you prepared a contingency plan in the event Gramm-Rudman-Hollings becomes reality? If so, please send a copy of your plans to this Committee.

Answer. The Institute is not developing such contingency plans at the present time. Contingency plans of this nature would be developed only if it becomes clear that reductions of this magnitude would occur.

Question. If cuts of this magnitude become reality, how will they be distributed: 1) intramural vs. extramural programs; 2) peer review system: would number of site visits be reduced? Would travel to NIH to study section meetings be affected? 3) Would NIH employees have to be furloughed? 4) What major programs would have to be cut back?

Answer. If a reduction of this magnitude were to occur, all programs of the Institute would be affected to some degree. The Institute would probably have to eliminate certain major population

studies and clinical trials; reduce the numbers of centers; and reduce research project grants.

Question. Please list the research programs of the highest priority that should not be cut and why.

Answer. A careful review of all programs would have to be conducted before it would be possible to say precisely what research programs would not be cut.

Questions Submitted by Senator William Proxmire

BLOOD DISEASES AND RESOURCES

Question. Dr. Lenfant, in comparing the 1986 crosswalk table contained in last year's justifications to the post-sequestration table carried in this year's justifications, I note that despite an increase of approximately $36 million above your budget request you will be spending about $7 million less than you originally planned on your blood diseases and resources program in fiscal 1986. Can you tell us why?

Answer. The FY 1986 column of the FY 1987 request has been adjusted to reflect a comparable transfer of $10,627,000 from the blood diseases and resources program to the Office of the Assistant Secretary for Health for AIDS research. On a noncomparable basis, the FY 1986 estimate after sequestration is $123,584,000 for the blood diseases and resources program, an increase of $3,718,000 over the FY 1986 request.

USE OF NEOMYCIN TO LOWER BLOOD CHOLESTEROL

Question. Last year you promised to look into reports that a common, inexpensive, antibiotic--neomycin--could be used to control cholesterol levels in the blood. It would be much less expensive than the current drug choice. Can you tell us now if neomycin has proven effective?

Answer. Neomycin is an antibiotic that was first shown to lower blood cholesterol concentrations in 1959. Over the past two years a number of studies indicate that the cholesterol lowering effect of neomycin reflects primarily a reduction in the concentration of the low density lipoproteins. The degree of cholesterol and low density lipoprotein reduction is comparable to that observed with the current drugs of choice for the management of hypercholesterolemia. Since the cost of neomycin is lower than that of the bile acid sequestrants--the current drugs of choice--and since the patient acceptance of this drug appears to be better, neomycin holds promise as an alternative therapy.

However, more information is necessary before a broad recommendation for its use can be made. Although the accumulated experience indicates that long term, low dose neomycin is safe, the total number of patients treated with the drug is too small to draw conclusive inferences about neomycin's safety. Neomycin is in the class of drugs known as aminoglycoside antibiotics, and this group of antibiotics are known to cause irreversible hearing loss and kidney damage. Therefore, careful evaluation of neomycin safety

is still necessary prior to approval by the Food and Drug Administration and widespread use by the public.

ARTIFICIAL HEART DEVICES

Question. Dr. Lenfant, last year you told us that within three or four years the Institute would be able to recommend an implantable electrically powered ventricular assist device--an artificial heart device. Are you maintaining that rate of progress? Can we expect to see such a recommendation within two or three years?

Answer. Within three years, we expect to have completed validation of electrically powered implantable ventricular assist devices capable of long-term circulatory support of patients with end-stage heart disease. Progress has been slowed somewhat by the difficulties associated with developing complete quality control and quality assuarnce programs, the need for design refinement, and the availability of hybrid electronic circuits. Some of these difficulties were anticipated because this program was designed to elicit problems before the devices were used clinically. The magnitude of the delays in availability of components of the electronic circuits was not expected and has set the program back several months. In spite of these problems, reliability studies are beginning and are scheduled to continue for two years. Assuming no other major problems, we expect that within three years considerable data will be available on the results of laboratory and animal testing of these electronically powered ventricular assist devices. With these data we expect to be able to make specific recommendations about these devices and begin clinical investigations.

HEART BYPASS OPERATIONS

Question. Dr. Wyngaarden, in his prepared statement, referred to advances in biomedical research that have reduced health care costs. One example he gave is the drug treatment of coronary artery disease as a substitute for coronary bypass surgery in certain patients. Your own Heart, Lung, and Blood Institute financed a study that found coronary bypass surgery was being performed unnecessarily in many cases. What hard evidence do you have to indicate that fewer coronary bypass procedures are being performed as a result of advances in the drug treatment of coronary artery disease?

Answer. The National Center for Health Statistics reported that there were 202,000 coronary bypass operations performed in 1984, as compared with 191,000 bypass operations in 1983. The increase in actual numbers, 11,000, represents the lowest percent change increase (5.8 percent) in the last five years. This 202,000 also includes second and third bypass procedures (redos) on an individual patient. The redo rate in the United States is between 10 and 15 percent of the total, or between 20,000 and 30,000 "redos" out of the 202,000 bypass procedures. This indicates that the number of primary isolated bypass operations is no longer on the increase. Advances in pharmacologic therapy for coronary artery disease, such as calcium channel blocking agents, are playing a leading role in the treatment of coronary disease, and would affect the number of bypass procedures performed in the course of a year.

TRANSFUSION MEDICINE

Question. Dr. Lenfant, in your prepared statment you refer to the screening of donated blood for the AIDS virus. I understand that the greatest risk posed by the use of donated blood products is the transmission of hepatitis. Can you tell us the extent to which this is a problem and what steps your Institute is taking to deal with it?

Answer. Viral hepatitis acquired from blood donors remains one of the most serious complications of blood tranfusion. The discovery, in 1968, that hepatitis type B could be detected in blood encouraged the hope that all infectious donors could be identified and post-transfusion hepatitis prevented. Although the transmission of hepatitis B virus is now almost completely preventable, transfusion-transmitted hepatitis continues to be a serious problem. Approximately 90 percent of the class of post-transfusion hepatitis in the United States are now caused by the agent or agents of Non-A, Non-B (NANB) hepatitis. Unfortunately, this form of hepatitis cannot be identified in the blood. Approximately 150,000 of an estimated 3,000,000 transfusion recipients in the United States will develop post-tranfusion hepatitis each year. It is estimated that approximately 75,000 will go on to develop some form of chronic infection and associated liver disease, and of these, about 10 percent, or 7,500, will develop cirrhosis.

The NHLBI is supporting several research projects under an RFP which focuses on the detection and inactivation of NANB hepatitis agent(s) in blood. One contractor is attempting to develop specific serologic assays for the detection of NANB hepatitis. Another contractor is evaluating the significance and natural course of elevated concentrations of liver enzymes in donors and the value of enzymatic assays as screening tests for the detection of NANB hepatitis. A third contractor appears to have developed a chemical method to inactivate NANB hepatitis virus in blood products and the procedure is undergoing further evaluation.

Finally, the Institute is considering the release of an RFP in FY 1987, encouraging the study of chronic post-transfusion NANB hepatitis. The objectives of this natural history study are to determine the clinical, biochemical and histological outcome of chronic NANB hepatitis in transfusion recipients.

700

National Institute of General Medical Sciences

STATEMENT OF DR. RUTH KIRSCHSTEIN, DIRECTOR
ACCOMPANIED BY WILLIAM T. FITZSIMMONS, EXECUTIVE OFFICER

PREPARED STATEMENT

Senator Weicker. Our next witness is Dr. Ruth Kirschstein, Director of the National Institute of General Medical Sciences.

Dr. Kirschstein, it is so nice to have you here. Your statement in its entirety will be included in the record. Please proceed.

[The statement follows:]

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STATEMENT OF DR. RUTH KIRSCHSTEIN

I am pleased to be here once again to present the programs of the National Institute of General Medical Sciences. These programs which support basic, untargeted biomedical research endeavors will continue to provide the knowledge through which specific diseases can be conquered. This ability to develop basic concepts and to rapidly translate the knowledge so generated into leads regarding those many diseases not yet understood has been telescoped from years to often only months. Yet, as each question is answered, new ones arise. What is clear is that progress builds on progress, and the future holds great promise for continuing advances. It is toward this future that the fundamental biomedical research and research training efforts supported by the National Institute of General Medical Sciences are aimed.

Nowhere is this natural flow of research endeavors from fundamental undifferentiated studies to disease-targeted activities better illustrated than by an account of the work of Drs. Michael Brown and Joseph Goldstein, this year's winners of both the Nobel Prize in Physiology or Medicine and the Lasker Award for basic medical research. Indeed, the story of the careers of Drs. Brown and Goldstein clearly demonstrates the vital role of NIH in biomedical research. Both men began their research careers in the intramural program of NIH. They then went to the University of Texas Health Science Center in Dallas, where their basic studies of cellular steroid receptors were supported by the NIGMS for a number of years. Gradually their collaborative studies focused on a particular steroid chemical, cholesterol, and they discovered a mechanism that controls its metabolism. Since such basic studies of cholesterol are critical to an understanding of, and the development of treatment regimens for, atherosclerosis and other cardiovascular disease, their research, originally supported by NIGMS, has been supported by the National Heart, Lung, and Blood Institute in recent years. Dr. Lenfant and I are pleased to thus illustrate the importance of all units of NIH in the continuum of biomedical research activities.

Pharmacological Sciences Program - Biorelated Chemistry

A field which has greatly contributed to our fundamental biomedical knowledge is chemistry. In 1985, the National Academy of Sciences (NAS) published a survey of Opportunities in Chemistry in which it outlined the past contributions of this field and the future advances which may lead to better health. As stated in the NAS report:

> Chemistry in the next decade will contribute to the solution of some of contemporary biology's most important problems. . . . Ultimately, our ability to control complex biological events will depend upon understanding at the molecular level. . . . Chemistry research relevant to the NIH mission concentrates largely in the National Institute of General Medical Sciences.

Much research in chemistry involves efforts to relate the physical and chemical behavior of organic compounds to their molecular structure. It deals with the pathways by which chemical reactions occur. Over the years, the NIGMS has supported many chemists

working in this area, including Nobel Laureates Drs. Herbert Brown, Roald Hoffmann, and Henry Taube. All of them helped to elucidate chemical reactions which are of importance to both health-related areas and industry.

Another significant area of chemistry is the synthesis of biologically important and useful substances which lead to products of far greater purity than can be obtained by starting with natural materials. Such synthesis has led and will lead, with even greater rapidity, to the development of new and more active therapeutic agents. For example, a chemist at the University of California in Berkeley has developed more efficient and direct methods for the total laboratory synthesis of steroids, a class of compounds that includes the anti-inflammatory agent, cortisone, and sex hormones, such as estrogen and progesterone. Steroids are chemicals in which atoms are arranged in a complex cyclic configuration. The team at Berkeley, using chemicals containing metals such as cobalt, has achieved the ability to catalyze or speed up the assembly of the needed atoms in cyclic fashion, directly and efficiently. This approach has been shown to be very versatile and is being used industrially to produce vitamin B_6 (a vital dietary constituent), as well as various pharmacologically active cyclic compounds, such as synthetic estrogens and corticosteroids.

Genetics Program

Another chemist, Dr. Jacqueline Barton of Columbia University, is designing molecules that can recognize and insert themselves into specific sites of the deoxyribonucleic acid (DNA) molecule, thus changing its structure. This may lead to the development of new cancer chemotherapeutic agents as well as a greater understanding of gene expression.

Identification of specific sites of expression of particular genes has permitted researchers to alter these genes, using a method called "site- directed mutagenesis." This technique first involves a determination of the sequence of the nucleotide building blocks of the gene being studied. Next, copies of these sequences are synthesized in the laboratory, except that each copy has a small altered fragment which causes a change, or mutation, at a specific site. These altered sequences are then combined with the host DNA, using recombinant DNA technology. What this does is to replace a normally occurring genetic instruction with another which is man-made. This new instruction may be designed to produce a specific protein--one which geneticists can tailor to particular requirements, for example, for the production of therapeutic products which may serve as anti-viral or anti-cancer agents.

Biophysics and Physiological Sciences Program

Furthermore, site-directed mutagenesis has been used extensively by biophysicists to test their theories as to the relationship of the structure of a particular protein to its function. If a mutation is produced at a single specific site on the gene coding for a protein, an altered protein is produced. Biophysicists thus can determine the relation of the altered protein structure to abnormal function; for example, the abnormal hemoglobin present in sickle cell disease or thalassemia.

This methodology is but one of a number of new techniques which, like highly sophisticated research instruments, have been developed by NIGMS grantees in order to permit the scientific advances which we have called the "biological revolution." Among these are rapid DNA sequencing, the chemical synthesis of nucleotide sequences, methods to isolate very large DNA fragments, as well as computer programs to identify these segments. Another new technique, two-dimensional nuclear magnetic resonance, has the potential to determine the positions of specific atoms in large molecular complexes of proteins and nucleic acids, which are the very "stuff of life."

Cellular and Molecular Basis of Disease Program

Scientists use these techniques, X-ray crystallography, recombinant DNA technology, and site-directed mutagenesis, along with disciplines such as chemistry and genetics, to gain more and more understanding of how the cell functions. What stands out is the dramatic expansion of the use of all these tools to learn about the organization of cells into tissues and organs. Fundamental questions still exist about how a multicellular organism develops. What is the time sequence of developmental events? How are they controlled? How do individual cells coordinate their behavior so that each plays its proper role at the proper time?

Recently, and very surprisingly, it has become clear that some answers to these questions may come from studies of groups of single-cell organisms, bacteria. It turns out that a certain type of bacteria called Myxobacteria undergoes, during its life cycle, primitive differentiation by single cells coming together into a multicellular form and that this is based on the exchange of chemical signals between the cells. These important studies by Dr. Martin Dworkin of the University of Minnesota and Dr. A. D. Kaiser of Stanford University, among others, make use of the remarkable genetic, biochemical, and molecular manipulations and analyses that are possible today, in order to determine what intercellular chemical signals are needed to coordinate the development and differentiation of the multicellular state. By making mutants of Myxobacteria and using recombinant DNA technology, Dr. Kaiser has been able to find that certain chemicals are required and must be available to all the individual bacterial cells in order for multicellular development and differentiation to take place. If the chemicals are not available to the mutant bacterial cells, such development is inhibited. Dr. Kaiser has found that this simple bacterial model is very easily manipulated and may well become the first system of multicellular development to be fully understood in terms of genetic and molecular mechanisms.

Research Training

It is abundantly clear that fundamental research is a most remarkable endeavor and one which is very rapidly providing answers to critical problems of health and disease. This enormous leap forward through the development of new technologies and instrumentation has been made possible by the creativity and continuum of endeavors of a broad spectrum of researchers. The NIGMS research training programs have had a very large role in the preparation of superb scientists at universities throughout the country, scientists who have made, and are continuing to make, important

advances both in untargeted basic research and in targeted studies such as those now being done by Drs. Brown and Goldstein, this year's Nobel Laureates. Indeed, while many NIGMS research grantees were supported under the Institute's research training programs, about one-half of those supported in NIGMS predoctoral training programs now are doing research which is supported by other, categorical institutes of NIH. Furthermore, as you know, a study by the National Academy of Sciences has shown that the young men and women trained in NIGMS-supported predoctoral programs have been more productive scientists than are those who did not receive NIH research training support. Of particular note is the Medical Scientist Training Program, which provides students with research training for the combined M.D.-Ph.D. degree. Individuals with this combined degree are among the most successful in obtaining research grant support from NIH.

Minority Access to Research Careers Program

One specialized training program about which I have told this Committee in past presentations is the Minority Access to Research Careers (MARC) Program. I am pleased to tell you that this year an evaluation of the MARC Honors Undergraduate Research Training Program has been completed by the National Academy of Sciences Committee on National Needs for Biomedical and Behavioral Research Personnel. The study found that MARC honors students are talented and highly motivated and that many of them would have been unable to finish their college curriculums without support from the MARC Program. Seventy-six percent of the MARC trainees who have graduated are enrolled in advanced graduate or professional studies. The percentage of biology majors at schools which have MARC Honors Programs has increased, and there are higher rates of bachelor's degrees earned in biology than previously. I have copies of this report available for members of the Committee.

I hope that I have conveyed some of the excitement of the advances in fundamental biomedical research, which are continuing to have an enormous impact on our understanding of ways to maintain and improve the health of the people of the world. The pace of discovery has been increasing but is far from its peak. There is so much yet to learn. The programs of NIGMS are aimed at providing the research manpower to keep up the momentum and at advancing knowledge of the fundamental cellular, molecular, chemical, and genetic processes so essential to developing better ways to prevent and treat disease.

Mr. Chairman, the 1987 budget request for this Institute is $471,533,000. I shall be pleased to answer any questions.

Biography of Dr. Ruth Kirschstein

October 12, 1926. Brooklyn, New York

Education: A.B., magna cum laude, Long Island University, 1947. M.D., Tulane University School of Medicine, 1951.

Professional History: 1951-52, Internship, Medicine and Surgery, Kings County Hospital, Brooklyn, N.Y. 1952, Assistant Resident,

Pathology, Veterans Administration Hospital, Chamblee, Ga. 1952-54, Resident, Pathology, Providence Hospital, Detroit, Mich. 1954-55, Trainee of National Heart Institute and Instructor in Pathology, Tulane University School of Medicine. 1956-57, Medical Officer, Resident in Pathology, Clinical Pathology, Clinical Center, NIH. 1957, Medical Specialty Board Certification, Pathology (anatomic and clinical pathology). 1957-60, Medical Officer, Pathologist, Laboratory of Viral Products, DBS, NIH. 1960-62, Chief, Section of Pathology, Laboratory of Viral Immunology, DBS, NIH. 1962-64, Assistant Chief, Laboratory of Viral Immunology and Chief, Section of Pathology, DBS, NIH. 1964-65, Acting Chief, Laboratory of Pathology, DBS, NIH. 1965-72, Chief, Laboratory of Pathology, DBS, NIH. 1971-72, Assistant Director, Division of Biologics Standards, NIH. 1972-73, Acting Deputy Director, Bureau of Biologics, FDA. 1973-74, Deputy Associate Commissioner for Science, FDA. 1974-present, Director, National Institute of General Medical Sciences, NIH.

Professional Organizations: American Association of Immunologists; American Association of Pathologists; American Society for Microbiology; Institute of Medicine, National Academy of Sciences.

Committee Memberships: Invited member of World Health Organization Expert Group on International Requirements for Biological Substances; Geneva, Switzerland, 1965 and 1971. Invited consultant to World Health Organization concerning problems related to the use of Poliovirus Vaccine, Live, Oral; Geneva, Switzerland, 1967. Member, Primate Research Centers Advisory Committee, Division of Research Resources, NIH, 1971-1975. Member, National Commission on Diabetes, 1975. Member, National Commission on Arthritis and Related Musculoskeletal Diseases, 1975. Chairperson, NIH Grants Peer Review Study Team, 1975-1976. Chairperson, PHS Genetics Coordinating Committee, 1976-1979. Member, Fogarty International Center Scholars-in-Residence Advisory Committee, 1977-1982. Member, NIH Coordinating Committee on Manpower, 1978-1983. Chairperson, PHS Task Force on Women's Health Issues, 1983-1984. Chairperson, PHS Coordinating Committee on Women's Health Issues, 1984-present. Member, NIH Advisory Committee for the IOM Study of the Organizational Structure of the NIH, 1983-1984. Member, HHS Executive Development Board, 1985-present.

Honors, Awards: Elected to Institute of Medicine, National Academy of Sciences, 1982. Doctor of Science, Honoris Causa, The Mount Sinai School of Medicine, 1984. Honorary Doctor of Laws, Atlanta University, 1985. DHEW Superior Service Award, 1971. PHS Superior Service Award, 1978. Presidential Meritorious Executive Rank Award, 1980. PHS Equal Opportunity Achievement Award, 1983. PHS Special Recognition Award--group award to PHS Task Force on Women's Health Issues (Dr. Kirschstein, Chairperson), 1985. Distinguished Executive Service Award of the Senior Executive Association, 1985. Presidential Distinguished Executive Rank Award, 1985.

SUMMARY STATEMENT

Dr. KIRSCHSTEIN. The programs of the National Institute of General Medical Sciences support basic, untargeted biomedical research endeavors which continue to provide the knowledge through which specific diseases can be conquered. What we have found is that the time it takes to develop these basic concepts and to translate them into information that can be directed toward specific diseases has been telescoped from years to only months.

The fundamental biomedical research, and research training efforts that we support are, indeed, an investment in the future. Nowhere is the natural flow of these research endeavors more clear than in the story which Dr. Lenfant did not have the time to tell you, but which I will tell you in a little bit of detail, about Drs. Michael Brown and Joseph Goldstein, this year's winners of the Nobel Prize in physiology or medicine, as well as the Lasker Basic Medical Research Award.

They began their fundamental studies by trying to learn how steroids and lipoproteins were being used as the building blocks for the membranes of cells. For a number of years, because these were very basic, untargeted studies, they were supported by the National Institute of General Medical Sciences.

Gradually, their collaborative efforts began to focus on a particular steroid chemical, cholesterol, and they discovered the mechanism that controls cholesterol's metabolism within the cells, and the receptor site for cholesterol on the cell surface.

Since these studies, then, had specific implications for atherosclerosis and other forms of cardiovascular disease, the research efforts that had, for many years, been supported by the National Institute of General Medical Sciences, then started to receive grant support from NHLBI.

Dr. Lenfant and I are very pleased to illustrate this continuum of research that clearly shows what happens when research efforts evolve from basic and undifferentiated work to more targeted studies.

In fact, everything that my colleagues have told you over the last 3 days has in one way or other demonstrated the importance of basic research. Dr. DeVita told you how cancer cells are now being dissected with molecular techniques. Dr. Williams told you about how the brain tissue of patients with Alzheimer's disease is being studied using recombinant DNA technology. Dr. Renault, this morning, told you about how markers, identified by the use of both gene mapping and restriction fragment length polymorphism techniques, all of which were developed by NIGMS[1] grantees, are being used to find the genes for various genetic diseases, such as cystic fibrosis and polycystic kidney disease.

These studies have clearly been made possible because of the fundamental discoveries of scientists supported by NIGMS. Today our Institute is beginning to support work on the next generation of advances, such as the development of more sophisticated research technologies, the rapid determination of DNA sequences, the isolation of very large DNA fragments, and more sophisticated x ray crystallography.

Another important factor in the dramatic expansion of all of these new tools is that it has been accompanied by a dramatic and important expansion in the support for, and importance of, chemistry. A recent National Academy of Sciences report predicts that chemistry will be the most important contributor to the solution of biomedical problems over the next 10 years. That report points out that NIGMS provides the major support at NIH for research in chemistry.

An important fact regarding these studies is that most of them originated in the untargeted, creative ideas of highly skilled, highly trained basic scientists. NIGMS, we are very proud to say, has played a very important role in preparing such scientists through its support of research training programs. Indeed, these NIGMS-supported programs providing basic research training have contributed about one-half of all of their graduates to research supported by the other categorical Institutes. These are the researchers who are now responsible for the advances that my colleagues have outlined to you.

Our programs are aimed both at providing the research manpower to keep up the momentum, and at advancing knowledge of the fundamental cellular, molecular, chemical, pharmacologic, and genetic processes that are so essential to developing better ways to understand and treat diseases. Nevertheless, we have to remember that there is still so much to learn if we are to maintain the flow of important research advances.

Mr. Chairman, the 1987 budget for NIGMS is $471,533,000. I would be very pleased to answer questions.

COMPARISON OF NIGMS AND NSF BUDGETS

Senator WEICKER. The first question comes from Senator Proxmire, and he says:

Dr. Kirschstein, as you pointed out in your prepared statement, your Institute supports basic, untargeted biomedical research endeavors. Because of your basic research role, I would like to explore with you and Dr. Wyngaarden a question I raised with Secretary Bowen.

As I calculate it, your Institute would take a cut of 2.9 percent below this year's Gramm-Rudman-Hollings budget for research into the cellular and molecular basis of disease if the President's fiscal year 1987 budget request were enacted.

On the other hand, the President has requested an 8.4-percent increase in the National Science Foundation's Molecular and Cellular Biosciences Grant Programs. As you pointed out in a record question last year, the basic distinction between your work on cellular and molecular biology and that of the NSF is that your work must be health related.

Can you tell us, then, why the NSF budget in this area is being increased by 8.4 percent while your budget is being cut by 2.9 percent?

Dr. KIRSCHSTEIN. Mr. Chairman, I am not privy to the decisions that were made regarding the National Science Foundation budget. Within the budget allocation that the National Institute of General Medical Sciences was given under the President's 1987 budget, we have maintained the ratio of the funds that are available to the Cellular and Molecular Biology Program at the same level, proportionate to our total budget, that it has been over the 12 years during which I have been the Institute's Director. However, I cannot tell you about those particular relationships.

Although our programs at NIH and at NIGMS are, indeed, emphasizing cell biology and molecular biology which is health related, the line of distinction between health relationship and other types of biology is very fine. We do find that some of the people who put in grant applications to our Institute also submit grant applications to the National Science Foundation.

We work extraordinarily closely, and we have excellent interrelationships, with all the staff of the National Science Foundation, and we make sure that these activities are totally coordinated.

CLINICAL TRIALS

Senator WEICKER. Does your Institute have any clinical trials?

Dr. KIRSCHSTEIN. No, sir; we do not conduct any clinical trials. As a basic research institute, that would not be appropriate. However, I think that it is important to realize that many of the research studies, particularly in our Pharmacology Program, but also in our Genetics, Cellular, and Molecular Basis of Disease, and our Biophysics and Rhysiological Sciences Programs, lead to the development of drugs and techniques, as well as preventive strategies, that might indeed be used in clinical trials. Future clinical trials that other Institutes might support often depend on the basic work that precedes them.

EFFECTS OF EMPHASIS ON RESEARCH PROJECT GRANTS

Senator WEICKER. It seems to me that it might be particularly appropriate to ask you the same question that I asked of other Institute directors as to the importance of grants, as to whether it has impacted negatively in other areas of your Institute's activities.

Dr. KIRSCHSTEIN. Our Institute relies on two basic mechanisms of support: We have a very large portfolio of research project grants, and we contribute significant support for research training. The life blood of our Institute in the research arena is the individual research grant, so we have welcomed the initiative to support more new and competing research grants.

However, within fiscal constraints, this has meant that some of the research training endeavors have had to be constrained a bit. This is particularly so for predoctoral research training, which involves paying tuition for pre-Ph.D. students. Such tuition is going up about 11 percent per year. This has had an impact on reducing the NIGMS research training efforts.

Senator WEICKER. It seems to me, I am sort of getting a picture here, I am a little bit worried that we might be building this fabulous high-rise of research grants, and then all of a sudden, one day, we are going to wake up and find out that the foundation in the basement can't support it. I think that is as well as I can describe it.

Dr. WYNGAARDEN. As I commented earlier, there has been a progressive shift since the early 1970's toward support of research grants, which we think has probably gone as far as is healthy. We have compressed the other mechanisms to the point where Dr. Lenfant is concerned.

You will get the same story from any of the other BID directors; they feel that a little better balance would help them with their total program. I think that this is particularly true in research training.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. I agree.

I have further questions for response to the record. Thank you very much, Dr. Kirschstein.

Dr. KIRSCHSTEIN. Thank you.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

BASIC RESEARCH LEADS TO LIFE-SAVING DISCOVERY

Question: In your budget justifications you describe how a basic research project on a form of yeast has resulted in life-saving information. Please briefly describe what this research has yielded. How many dollars were invested in the project, and finally, how much money may be saved yearly because of the results of this research?

Answer: You are referring to the work of Dr. David Feldman, an NIGMS grantee at Stanford University. Dr. Feldman's research on yeast has yielded information of importance to health in two separate areas. In one case, he found that South American blastomycosis, a serious and sometimes fatal lung disorder caused by a fungus endemic to Latin America, is 75 times more common in men than in women, despite the fact that both sexes have essentially the same exposure. Dr. Feldman found that the female hormone, estrogen, binds to a protein on the fungus and prevents its conversion to the form necessary for an infection to occur. Thus, women appear to have a natural protection against the organism involved. This disease is the most common systemic fungal disease in Latin America and ranges from southern Mexico to northern Argentina. Dr. Feldman's research not only provides an explanation as to why women are relatively resistant to this disease, but also opens the way for possible preventive strategies in those male populations especially at risk for contracting blastomycosis. Indeed, given the relatively low cost of suitable therapeutic drugs to deal with this problem, now that it is better understood, the potential for dollar savings is substantial.

The second area in which Dr. Feldman's work has produced life-saving information, and the one specifically mentioned in the Institute's budget justification materials, is related to stress. Dr. Feldman performed a series of basic research studies utilizing yeast and fungi in an attempt to define the role that steroid hormones (for example, estrogen) and their receptors play in one-celled organisms. The results of these studies led him to studies in rats and then humans, and finally to the discovery that the anti-fungal drug, ketoconazole, inhibits steroid synthesis. This is important because ketoconazole is similar to the sedative, etomidate, the use of which has been reported to result in increased death rates in patients in intensive care units. Dr. Feldman found the reason--etomidate, like ketoconazole, inhibits steroid synthesis, thereby reducing the ability of patients to tolerate hemorrhage and infection, both frequent occurrences following surgery or injury. This discovery has led physicians to use a sedative drug in these situations which does not inhibit steroid synthesis—thereby reducing the risk of death or life-threatening complications.

The National Institute of General Medical Sciences provided $557,000 in support for Dr. Feldman's research over a period of four years. This is in addition to an undetermined amount of support for preliminary work in this area provided by other NIH components.

Dr. Feldman's research findings are fairly recent and estimates of the dollars saved as a result of his discoveries are

difficult to produce at this stage; but it is certain that the Federal Government's investment in his work will be repaid many times over each year. Beyond this, of course, is the fact that a considerable number of lives will be saved.

RECOMBINANT DNA

Question: This Institute supported research in the 1960's that developed the important technology of recombinant DNA. Can you give us a few examples of the value of this technique and how it has impacted upon disease.

Answer: A number of commercial concerns are using recombinant DNA technology to develop and produce substances which were previously unavailable, rare, or prohibitively expensive, as well as substances which are of greatly increased purity. The first such commercially produced substance was human insulin. Human growth hormone is also now available. More recently, human antihemophilic factor VIII has been produced using recombinant DNA technology. This is promising to markedly reduce the cost of this material, so important to the well-being of hemophiliac patients, as well as the risks of AIDS virus infection, since factor VIII is, at present, prepared from pooled human blood. In addition, tissue plasminogen activator, the most promising new chemical for dissolving blood clots, is now being produced using this technique.

Question: How much money was invested in the research that developed the technology?

Answer: Many of the basic ideas and tools for recombinant DNA technology were developed in the 5 year period between 1969 and 1974. In those 5 years, the NIGMS made research grant awards through its Genetics Program totaling about $350 million--roughly 10 percent of which was invested in the grants through which recombinant DNA technology was developed.

Question: Can you estimate the financial impact of this technology in the development of new products, new vaccines, new treatments for disease?

Answer: There are more than 200 biotechnology companies in the U.S. Most of these companies have, as yet, not developed marketable products, but there is the expectation that medically important materials, including vaccines, biological modifiers (such as interferon) and peptide hormones, will, in the next few years, be readily produced, tested, and introduced to the market place. According to the journal Science, investments in biotechnology companies have mushroomed in recent years, reaching an estimated $2.4 billion in 1985. The great interest of investors in such companies is an indication of their expected potential.

To illustrate this potential, consider the recent successful production, in bacteria, of human antihemophilic factor VIII. Hemophilia A is a relatively rare disease, afflicting only about one out of every 10,000 males in the population. Yet, the current treatment for this disorder, which involves the use of blood-derived factors, costs the nation almost $100 million/year in health care

costs (up to $10,000 per patient per year). The potential availability of large amounts of antihemophilic factor VIII, produced through the use of recombinant DNA techniques, now holds out hope for an effective treatment that could result in annual savings to the health care system of perhaps $90 million/year. Even greater savings can ultimately be expected as a result of the production of more economical treatments for the more common diseases, such as cancer, diabetes, and heart disease. To this must also be added the productive man-years saved as a result of treatments for previously untreatable disorders, treatments made possible as a result of recombinant DNA technology.

Interestingly, the greatest economic impact of recombinant DNA techniques may occur in agriculture--with the potential for "custom-designed" crops now on the horizon. The possibilities range from the development of crops which are disease and pest resistant, to modifying cereal plants, such as wheat, corn, and soybeans, so that they can manufacture their own fertilizers. Within the past month, an NIGMS grantee at Stanford University (Dr. Virginia Walbot) reported the development of a new recombinant DNA technique, which will enable scientists to move genetic materials more readily from one plant species into another--an advance that could, for example, allow the insertion of cactus genes into wheat, thereby reducing the need of wheat for water.

NEW METHOD OF CHROMOSOMAL LOCATION

Question: Can you briefly describe the implication of the new method of identifying a gene that has been developed by Dr. Hogness of Stanford University.

Answer: Several years ago scientists recognized that normal variations occur in DNA sequences. These variations are known as restriction fragment length polymorphisms (RFLPs) and are detected by enzymes that recognize and cut only specific DNA sequences. If a particular RFLP is located near a disease-related gene, it may be possible to use it as a marker for the presence or absence of that gene in an individual. Use of markers for such disease-related genes has made it possible to diagnose a number of serious genetic defects even though the gene itself, or its products, are not yet known. Defects that have been diagnosed in this way include Huntington's disease, Duchenne's muscular dystrophy, polycystic kidney disease, cystic fibrosis, and at least one form of cardiovascular disease, familial hypercholesterolemia. Once a marker is found for a disease-related gene, the next goal is to identify and isolate the gene in order to determine the exact cause of the disease and develop rational therapies.

One strategy for identifying disease-related genes is based on the work of Dr. Hogness and his colleagues at Stanford University. Although their work was originally done to map Drosophila (fruitfly) chromosomes, their techniques of chromosome "walking" and "jumping" are applicable to studies of human chromosomes as well. In chromosome walking, one isolates one segment of DNA that overlaps the RFLP, then another and another, until a segment is found that corresponds to the disease-related gene itself. Although, in principle, this seems straightforward, "walking" along the distance involved, for example, between the Huntington's disease gene and its marker,

has proven to be both difficult and time-consuming. Chromosome "jumping," which allows one to skip entire stretches of DNA, can be done if it is known that certain conditions, such as duplication of DNA sequences, occur in the area between the marker and the disease-related gene. Chromosome "walking" and "jumping," along with other new methodologies, should make it feasible to identify disease-related genes when an RFLP marker is known but the specific gene has not yet been located.

Question: Is it possible to relate the cost of this research to possible cost savings for the future?

Answer: It is impossible to estimate possible cost savings to be derived from this work. However, genetic diseases are estimated to account for 15-20% of health care costs. Being able to prevent or treat some of these diseases should reduce these costs considerably.

GENETIC DISEASE RESEARCH

Question: I understand that through the technique known as gene mapping the location of a disease-causing gene can be identified. You have indicated this knowledge could lead to early detection of such diseases as Huntington's disease and cystic fibrosis. What will early detection do in these cases? Has any therapy been developed that would correct or normalize the gene?

Answer: Early detection of genetic diseases has several possible advantages. First, prenatal diagnosis makes it possible for parents to continue a pregnancy with the assurance that their offspring will be free of the disease. Second, for certain diseases, early diagnosis enables physicians to institute appropriate treatment of affected infants immediately after birth to prevent or alleviate serious symptoms. Finally, in conjunction with research to characterize the disease-causing gene, other research regarding replacement with the correct gene or gene product may provide a possible cure for certain of these diseases.

To date, therapies in man have not been developed to correct or normalize genes. A great deal of research, however, is currently being conducted, and it is anticipated that such corrections will be possible in the future.

Question: How much research effort is being supported in this area, and is it enough?

Answer: The NIGMS, for many years, supported the basic research which laid the foundation for the strategies now being used for the early detection of such disorders as Huntington's disease and cystic fibrosis. Much of the work related to such strategies is now supported by the appropriate categorical institutes. Currently, the NIGMS Genetics Program is providing approximately $35 million per year in research support for projects related in some way to the painstaking process of mapping all the genes of the human genome, most especially through the development of faster, more effective methods to identify them. This amount is adequate to fund the most promising studies.

TRAINING

Question: Your Institute is responsible for the major portion of the research training awards made by NIH. I am disturbed to see that you are requesting zero dollars for new and competing training grants and fellowships. Are you phasing out support for research training?

Answer: The NIGMS is not phasing out support for research training, despite the lack of funds for new and competing training awards in the Institute's 1987 budget. Indeed, recent studies of the Institute's training program activities--including the Institute's Minority Access to Research Careers Program--performed by the Institute of Medicine/National Academy of Sciences (IOM/NAS) have clearly shown the value of its research training activities in terms of producing excellent and highly dedicated research scientists. The NIGMS budget provides $52.9 million for the support of 2,797 trainees in 1987.

Question: How do the number of trainees and fellows that you are proposing to support compare to the number recommended by the National Academy of Sciences in its 1985 report on future personnel needs?

Answer: We currently estimate that the Institute will fall short of the IOM/NAS recommendation regarding the support of predoctoral students in the basic biomedical sciences by about 800 trainees.

Question: What is the impact of the proposed budget on the minority areas training program and medical scientist training program compared to 1985 levels?

Answer: The President's 1987 budget provides funds for 395 trainees under the Institute's Minority Access to Research Careers (MARC) Program, 83 fewer than the 478 trainees supported in 1985. The number of trainees supported under the Medical Scientist Training Program, which is designed to address the national shortage of physicians who have had research training, is similarly reduced over this two year period, dropping from 683 trainees in 1985 to 597 in 1987.

Question: I have been saying that the number of people wishing to enter careers in biomedical research has been declining since 1976. Can you discuss what, in your professional judgment, will happen 10-15 years from now if we don't reverse this trend?

Answer: In its 1985 report, Personnel Needs and Training for Biomedical and Behavioral Research, the IOM/NAS states that, "NRSA training grants and fellowships are integral parts of the overall biomedical and behavioral research programs in this country and play key roles in maintaining the vitality of those programs." This is clearly true; and we must, as a nation, continue to recruit an adequate number of our best and brightest young minds into biomedical research careers if we are to maintain the momentum produced by the powerful system we now have in place.

Question: What are some of the specific problems causing this decline, and what should we be doing about them?

Answer: The IOM/NAS report has taken note of the shrinking pool of postdoctoral trainees in the basic biomedical sciences, and has estimated, in its recent report, that a total of 9,350 postgraduate bioscience trainees would be required by the year 1990 to accommodate projected needs for academic faculty. This compares to a pool of about 7,900 postgraduate trainees in 1983. Roughly 40 percent of such trainees are currently supported through NRSA research training awards. Similarly, the IOM/NAS has expressed concern over declining enrollments in predoctoral (pre- Ph.D.) biomedical research training programs, noting a 12 percent drop in NRSA predoctoral awards in the basic biomedical sciences since 1980.

A further problem is that the interest of physicians in biomedical research has declined. This is illustrated by a report recently issued by the National Science Board which notes that while, in 1972, M.D.s represented 55 percent of the medical school faculty members serving as principal investigators on NIH and ADAMHA research grants, this number had dropped to only 40 percent by 1982--10 years later.

There are a number of reasons for this situation. First, medical students, often deeply in debt upon graduation, are being lured into private practice. Second, young people are alert to the fact that biomedical research funding is increasingly competitive. And third, traineeships are becoming fewer in number.

I believe, as stated in the IOM/NAS report, that "sharp year-to-year variations in training levels are unnecessarily disruptive," and that one of the best things we can do is convince young people that the Federal Government is serious about providing both stable and adequate long-term funding support for research and research training.

NIGMS is addressing the decline in the number of physician-researchers with the Medical Scientist Training Program (MSTP), which has been extremely successful to date in producing a cadre of top-flight investigators having both basic and clinical research training. Because the MSTP, like all research training programs, provides for tuition and stipends, individuals graduating from this program with the combined M.D.-Ph.D. degree do not face the problem of starting out deeply in debt; and, to date, approximately 70 percent of them have entered careers in biomedical research. The President's budget provides support for an estimated 597 MSTP trainees in 1987, at a cost of $13 million.

5-YEAR FUNDING PERIOD

Question: There has been some discussion about extending the traditional 3-year grant commitment to 5 and 7 years. What would be the benefits of an extension to a 5 or 7 year commitment?

Answer: The average length of a research project grant in NIGMS is currently about 3.5 years. There has been a growing feeling that this period is not long enough in many cases. One concern is that this relatively short grant period discourages innovative and speculative research, because if an experiment fails, the

scientist does not have time to try another approach before grant funding runs out. Another concern is that scientists have to spend too much time writing research grant applications at frequent intervals, instead of concentrating on their research endeavors. Both of these concerns would be overcome by longer grant periods of 5 or 7 years.

Question: How would the choice be made?

Answer: It is our opinion that a larger proportion of grants should be for 5 years than is currently the case. Some research projects undoubtedly are of such a nature that they can be completed in 3 years, and some investigators may merit only a 3 year grant period until they can show that they can pursue a line of research effectively. In many cases, however, we feel 5 years would be an appropriate period to encourage maximal productivity and creativity.

A 7-year grant, or indeed a grant for any period longer than 5 years, would be an exceptional situation. We feel such a grant should be reserved for investigators who have proven themselves to be outstanding researchers over a long period of time--at least 10 years. These would constitute only a small percent of our grantees.

Question: Would it require an increase in the Research Grant funding base?

Answer: If the total number of NIH grants were kept constant, there would be no effect on the research grant funding base. However, the number of noncompeting grants would increase, and thus the number of competing grants would have to be decreased to maintain the same total number of grants.

Question: What are your views on such a change?

Answer: Both the staff of the NIGMS and the members of the National Advisory General Medical Sciences Council have been deliberating regarding this issue for some time, and we think that for some research projects longer grant periods make sense.

RESEARCH GRANT REDUCTIONS

Question: I understand that the NIH normally makes small adjustments in the research budgets recommended by the peer review process. The FY 1986 appropriated budget did not provide for full costs of research grants, and Gramm-Rudman has forced you to reduce the budget by a further 4.3%. How much below recommended levels are you having to go at the present time?

Answer: Because the reductions required by sequestration were imposed in the middle of the fiscal year, the reductions we will have to negotiate for grants still to be awarded are greater than they would be otherwise. For noncompeting grants, we are negotiating reductions averaging 6.3%; for competing grants, the average will be about 14%.

Question: What areas of each research budget are likely to bear the brunt of these reductions?

Answer: In general, the reductions are spread over all research budget categories. However, because of the magnitude of the cuts involved, the personnel category has to be cut in almost all cases.

Question: What effect do these reductions have on the ability to conduct the actual research?

Answer: While small reductions in grant budgets can usually be absorbed without a major impact on the research, reductions of the size being made this fiscal year can have a serious impact. It is our experience that, on the average, a reduction of up to about 10% will slow down the rate of progress on a grant, but not disrupt the project enough to cause it to be abandoned entirely. However, reductions of greater than 10% have a more serious impact because they require the loss of key personnel and thus the project cannot proceed as planned. Indeed, some aspects of the project may have to be dropped altogether.

FACULTY SALARIES AS PART OF RESEARCH BUDGET

Question: I understand that a portion of full time faculty salaries are traditionally paid for out of a research grants budget. Am I correct in assuming that the percentage of that faculty member's salary paid for by the grant is equal to the time he spends working on that specific grant?

Answer: An investigator is entitled to claim salary compensation from a research grant in proportion to the percentage of time he spends working on that grant. While many investigators do claim, on the grant, the full amount of salary to which they are entitled, many do not, but ask for lesser amounts or, in some cases, no compensation at all.

Question: How is this percentage of effort determined, and is this percentage ever reviewed by NIH in its audit procedures?

Answer: The percentage of effort that an investigator charges to the grant basically is proposed by the investigator and his institution in the grant application, based on their best judgment of what is needed to perform the research. The study section, or peer review group, then reviews the proposal and modifies it as appropriate, based on the reviewers' experience with similar research efforts. All investigators are required to submit time and effort reports to their institutions and charges to the grants are based on these reports. During audits by the Department of Health and Human Services, these time and effort reports are one of the items that are investigated. The National Institutes of Health itself does not audit the effort devoted to a grant unless there are allegations of improprieties that come to its attention. In such a case, the Division of Management Survey and Review, NIH, investigates the allegations.

Question: I would like to receive a report that would show the change in the percentage of salary of full time tenured faculty paid for by research grants over the past decade in your Institute.

Answer: A report is being prepared and will be forwarded to the Committee in the near future.

GRAMM-RUDMAN

Question: The budget cuts that may be forced by Gramm-Rudman are supposed to be equally applied by program as identified by the appropriations bill and its report. How much direction and flexibility should the Director of a research Institute have in order to minimize the indiscriminate impact of across-the-board cuts?

Answer: From the point of view of managing the appropriated funds in the best way toward fulfilling the mission of the NIGMS, it would be useful for the Director of the Institute to be able to authorize reprogramming between mechanisms and programs.

IMPACT OF BUDGET REDUCTION

Question: The President's budget proposal for FY 1987 reduces your budget by $43,232,000 under FY 1986 appropriated levels. Gramm-Rudman-Hollings, if triggered, could reduce your budget even further--maybe by as much as 20 percent.

I've known this would reduce the number of grants, possibly the size of grants, centers, training, etc., etc. Can you give us some idea of the impact of these reductions on the kinds of research that would be stopped or lost?

Answer: The President's Budget was developed within overall deficit targets that would preclude the need for any 1987 sequestration. If the magnitude of reductions you mentioned were necessary, we would make every effort to honor our commitments to the extramural community, thus necessitating considerable reductions in, or possible elimination of, numerous programs and new starts that would otherwise be funded by our four scientific programs.

Question: What impact might this have on the health of our citizens five and ten years down the road?

Answer: It would slow the development of new methods of diagnosis, treatment, and prevention for a number of diseases, including genetic and developmental disorders.

Question: Can you discuss your contingency plans if these massive budget cuts should come to pass?

Answer: We do not have specific contingency plans at this time.

RESEARCH PRIORITIES VS. REDUCED BUDGET

Question: If the budget cuts become a reality (NIGMS would lose $43 million), how would you prioritize your research responsibilities, and what role would the Advisory Council play in the prioritization?

Answer: The research supported by NIGMS is prioritized in a number of ways. In preparing the budget proposals that go to Congress each year, the Institute tries to identify both the scientific opportunities and the needs in each program area, assuming that applications of equal scientific merit will be awarded during the year in all programs. The overwhelmingly major part of the Institute's research support budget is dedicated to individual investigator-initiated research project grants. The Congress, by its appropriations and report language, also expresses its priorities. It has recognized that the fundamental, undifferentiated research projects supported by the Institute's programs concern fields of biomedical science that together form a continuum with indistinct demarcations. In addition, the peer review system, through its initial review groups, assesses the scientific merit of investigator-initiated grant applications and assigns priority scores accordingly. Beyond all this, the National Advisory General Medical Sciences Council undertakes the second-level review of all research grant applications and offers advice on particularly promising research directions as guidance to the Institute staff. While these recommendations are not absolutely binding, they form the basis for the final decisions made by the Institute.

The above process has been and will be followed regardless of the size of the research grant budget.

IMPACT OF SEQUESTRATION IN 1987

Question: If the automatic provisions of Gramm-Rudman-Hollings are triggered in FY 1987, your Institute may well have its budget reduced by 20-25%. Have you prepared a contingency plan in the event Gramm-Rudman-Hollings becomes reality? If so, please send a copy of your plans to this Committee.

Answer: We have not developed a formal contingency plan.

Question: If cuts of this magnitude become reality, how will they be distributed: (1) intramural vs. extramural programs; (2) peer review system; Would number of site visits be reduced? Would travel to NIH to study section meetings be affected? (3) Would NIH employees have to be furloughed? (4) What major programs would have to be cut back?

Answer: The answers to your questions are as follows:

1. Essentially all the reduction would be taken from extramural programs, since the NIGMS intramural program represents only 0.2 percent of the Institute's budget.

2. Peer review site visits and meeting travel are now reduced to the minimum; further reductions cannot be taken in this area.

3. Every effort will be made to avoid staff furloughs. However, depending on the extent of any cuts that might occur, reduction of staff through attrition or furloughing might become necessary.

4. All the research programs supported by the Institute would have to be carefully reviewed before appropriate decisions could be

made regarding the extent of reduction in some and the elimination of others.

Question: Please list the research programs of the highest priority that should not be cut and why.

Answer: Important and exciting work is being supported by all of the Institute's research programs, primarily through the investigator-initiated research project grant mechanism. All of these programs would have to be cut. It would be desirable to minimize further reductions to the Genetics Program, however, in order to assure adequate progress toward the elimination of genetic diseases.

Questions Submitted by Senator William Proxmire

GENETICS RESEARCH

Question: Dr. Kirschstein, it would appear from your budget that your genetics research program is not as active at this point as some of your other research endeavors. For example, of the $35 million we added to your 1986 request--I'm talking in post-Gramm-Rudman-Hollings terms--only $441,000 was added to your genetics program. Furthermore your proposed 1987 genetics budget of $148,920,000 is about 5 percent below your 1984 budget for this activity whereas your other 1987 research requests show substantial increases over 1984 expenditures.

I certainly don't mean to be critical of you for placing an emphasis on other research areas. In fact, its reassuring to see that you are making tough priority-setting decisions. But is it fair to say that research in the area of genetics has cooled off a bit at your Institute?

Answer: As noted, the funds allocated to the Genetics Program were less in FY 1986 and are decreased also in the proposed FY 1987 budget. However, this does not indicate that the "area of genetics has cooled off." What it does signify is that many technical developments and scientific advances emanating from genetic research, such as recombinant DNA methodology, have led both to an explosion of knowledge in other scientific areas (such as cell biology, the pharmacological sciences, biochemistry, and biophysics) and to a broader application of genetic techniques to research in these other areas. The use of these methodologies derived from genetics research has led to greater and greater research opportunities in these other fields. Within the current fiscal constraints, we are attempting to exploit the opportunities in these other fields, while at the same time, supporting the best new research opportunities in genetics.

It is an interesting phenomenon that as genetic research methodologies and technologies have been further developed and used in other areas, the boundaries between the various scientific fields (e.g. genetics, pharmacology, and cell biology) have become less precise and more and more blurred.

I would also point out that more than one-third of the funds available to the NIGMS for research grants have been allocated to the Genetics Program--an indication of the continued importance of genetics research.

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

STATEMENT OF DR. DUANE ALEXANDER, DIRECTOR

ACCOMPANIED BY JOEL R. HEDETNIEMI, EXECUTIVE OFFICER

INTRODUCTION OF ASSOCIATE

Senator WEICKER. Our last witness will be Dr. Alexander, Director of the National Institute of Child Health and Human Development.

Dr. ALEXANDER. Mr. Chairman, I am accompanied by the Institute's Executive Officer, Mr. Joel Hedetniemi.

The anniversaries that are going to be occurring in 1987 have been mentioned prominently several times in these hearings. 1987 will mark the 25th year since NICHD was established by the Congress to address some of the most important public health problems in the Nation. The statement that I have submitted for the record outlines a number of the problems, and our approaches to them. I would like to highlight just a few of them.

REDUCING INFANT MORTALITY

Foremost among these is improvement in pregnancy outcome and reducing infant mortality. Through research we are now able to save about one-half of the babies that are born weighing as little as 2 pounds, but the cost and complications of low birth weight mean that our primary emphasis must be on prevention.

The networks of maternal-fetal medicine units, and neonatal intensive care units that we have been discussing as part of our low birth weight initiative will become operational this month, and will provide a system that will quickly test new obstetric and neonatal techniques to prevent low birth weight or improve the outcome of these low birth weight infants.

BIRTH DEFECTS

Birth defects are the leading overall cause of infant mortality. Our scientists have identified some of the genes involved in earliest embryonic development, and are studying in animal models how these genes turn on or off, or misfunction, to cause malformation.

SUDDEN INFANT DEATH SYNDROME

Sudden infant death syndrome is the leading cause of death from 1 month to 1 year of age. We have demonstrated that this is not linked to

DPT immunization, as some have claimed, and we are encouraging scientists to pursue new leads on this mysterious condition.

CHILDHOOD INJURIES

Injuries become the leading killer and disabler of children from 1 year of age well into adulthood. Our behavioral scientists have developed effective ways to reduce automobile injury and scalding among children, and are extending this work to other areas of injury prevention.

MENTAL RETARDATION

Mental retardation is the major reason for children not to achieve their full potential, but we are steadily adding to the number of causes of mental retardation that are eliminated. A major cause of acquired mental retardation in this country now is meningitis due to *Hemophilus influenzae/*infection. Our intramural scientists have developed a vaccine that we expect will be protective against this disease in infancy, and we will be launching a field trial of this, along with our new pertussis vaccine, this year in Sweden. I predict that this disease will be the next cause of mental retardation that we eliminate.

INHIBIN

One-half of the pregnancies in this country are still unintended. One of our grantees, Nobel Prize laureate, Dr. Roger Guillemin, a few months ago, isolated and determined the structure of inhibin, a protein that we think will form the basis for a new contraceptive. This long sought substance specifically inhibits sperm formation and ovulation, without affecting other sexual functions, and we are going to be pursuing work on inhibin as part of our contraceptive development initiative.

NICHD FISCAL YEAR 1987 BUDGET REQUEST

The work of this Institute helps to assure the birth of healthy children, wanted children, and provides an opportunity for all children to reach their full potential. Our request for fiscal year 1987 is $309,119,000. I will be pleased to answer any questions that you may have.

PREPARED STATEMENT

Senator WEICKER. Thank you. We will insert your complete statement in the record and then proceed to some questions.

[The statement follows:]

Statement of Dr. Duane Alexander

There are many complex biological and behavioral processes involved in the successful achievement of each major step in the life cycle--reproduction, pregnancy, birth, and development from infancy and childhood to adulthood. There are also many opportunities for problems to arise. Because each step is so fundamental to the development of a healthy, functional adult, difficulties during any of them can result in some of the most devastating and costly human problems: infant mortality, birth defects, injuries, learning disorders, mental retardation, infertility, and unintended pregnancies.

Herein lies the difficult and challenging research mission of the National Institute of Child Health and Human Development (NICHD). Our research aims to develop knowledge that will assure that each child is born healthy, wanted, and able to develop to his or her full potential. There is no more fundamental desire of the American people than wishing this for their children. Our guiding belief is that by understanding normal development, scientists will be able to devise treatments for disease and dysfunction in reproduction, birth, growth, and development, or better yet, to prevent these problems from arising.

Infant Mortality and Low Birth Weight

The United States' international ranking in infant mortality is not in keeping with our commitment to the health of our people. This poor ranking (15th) is attributable almost entirely to low birth weight, which is associated with 2/3 of all infant deaths, is twice as frequent among blacks as among whites, and is the preeminent problem in child health in the United States today.

In 1984, the NICHD began a major special initiative: an expanded research program in the prevention of low birth weight. The initiative includes increased research on intrauterine growth retardation (IUGR) and prevention of premature labor, the two factors responsible for low birth weight. As part of this initiative, the NICHD recently funded two new research centers to study fetal growth retardation. We are also aggressively pursuing the causes of premature labor and ways to prevent it. For example, in one clinical trial more than 17,000 pregnant women are being screened for asymptomatic genitourinary infections believed to be associated with premature labor, and studied to determine whether treating these infections will prevent premature delivery. We are also beginning studies of new devices that detect premature labor very early and allow intervention to stop it. Because maternal behavior is such an important factor in low birth weight, our scientists have helped design and fund an intervention study in the District of Columbia intended to identify high-risk women early in pregnancy, encourage them to enter early regular prenatal care, and eliminate behaviors such as smoking and alcohol consumption that increase the likelihood of low birth weight and infant mortality or morbidity.

To provide an ideal system for developing and testing new obstetric and behavioral approaches to managing complicated pregnancies and preventing low birth weight, the Institute recently established a national network of seven maternal-fetal medicine units. A companion network of neonatal intensive care units will provide a setting for clinical trials by neonatologists and nurses to investigate the safety and effectiveness of new treatment and

management methods for critically ill infants in improving survival and preventing long-term disability. Since large numbers of patients will be seen through these networks, investigators will be able to evaluate specific drugs or treatments more rapidly, coordinate their findings, and expedite their introduction into practice.

Birth Defects and Genetic Diseases

Birth defects and genetic disorders are a major contributor to infant mortality and lifelong morbidity, but have been unusually difficult to approach experimentally. This situation is now changing due to the new research tools provided by molecular biology, and this field has become one of the most exciting and promising in the Institute. Our intramural and extramural scientists are using animal models to study, at the level of gene structure and expression, the basic processes involved at the earliest stages of development that determine proper or improper organ and limb formation. We are also developing and refining techniques to insert new genes into cells with gene defects, and to control their action correctly. This is the basic research that will lead eventually to human gene therapy. To foster this research, the NICHD recently established a repository where human DNA segments will be collected, stored, and distributed to scientists around the world. The repository will eventually store copies of most of the 100,000 human genes and will enable scientists to locate and easily acquire the specific pieces of human DNA they need to locate genes on specific chromosomes, distinguish normal from abnormal genes, insert genes into chromosomes, and eventually treat genetic diseases.

Sudden Infant Death Syndrome

Once infants pass the critical newborn period, Sudden Infant Death Syndrome (SIDS) is the leading cause of death up to one year of age. The NICHD supports a comprehensive research program to discover the causes and identify the risk factors for SIDS. With the completion of our large cooperative epidemiologic study of SIDS--which, among other findings, provided clear evidence that DPT immunization is not linked to SIDS--our SIDS research program is entering a new phase. A recently issued Request for Grant Applications on SIDS encourages investigators to focus efforts on neural control of cardiorespiratory function, particularly at the brainstem level. We are concerned that scientists in this field have become discouraged by lack of positive findings, and we are determined to rekindle new efforts and approaches to SIDS in enhancing this research program.

Mental Retardation and Learning Disabilities

Mental retardation has been a leading concern of the NICHD since the Institute was established. Much of the nation's research on mental retardation and learning disabilities is conducted in a network of Congressionally established Mental Retardation Research Centers supported by NICHD. Studies in the biomedical sciences supported by the Institute have led to interventions that are highly effective in preventing mental retardation from a few of the many biological causes, such as congenital hypothyroidism. NICHD-supported studies applying the behavioral sciences to the much larger category of socio-cultural-familial mental retardation have suggested that early behavioral interventions may be effective in reducing the likelihood of mental impairment in high-risk infants and children. These studies now need to be validated and extended to include neurodevelopmental stimulation.

The excitement of the "new biology" carries over into the field of mental retardation and learning disabilities as well. Major advances have been made in our ability to study normal and abnormal development of the brain and nervous system, where we must look for the underlying causes of much of the mental retardation and learning disabilities that remains of unknown origin. The new tools of molecular biology are being applied to diagnosing and eventually preventing mental retardation due to genetic defects. A conference that we will convene this fall will provide the Institute with the best advice the scientific community can give as to how best to use these new technologies in our assault on these conditions that prevent children from reaching their full potential.

New Vaccines for Illnesses of Infancy and Childhood

Whooping cough, typhoid fever, and meningitis due to Hemophilus influenzae are still responsible for illness, death, or permanent disability in many children. Fear of side effects from the existing whooping cough vaccine made from whole pertussis bacteria is inhibiting its use, and the disease is returning. NICHD intramural scientists have recently purified the single component of the bacteria that they believe is sufficient to produce an entirely safe and effective vaccine. They are about to start field trials of their new vaccine in Sweden, where without vaccine use pertussis has reached epidemic proportions.

These same scientists have succeeded in developing new vaccines against typhoid fever and H. influenzae. The new typhoid vaccine, just entering field trials in India and Nepal, is expected to have minimal side effects and produce lifelong immunity. Despite effective antibiotics, H. influenzae remains a serious cause of sickness and death in infants and is a leading cause of acquired mental retardation. A recently licensed vaccine based on earlier work of these NICHD scientists is effective in older children but not under two years of age, the time of greatest risk. They have now produced a modified vaccine that is effective in infant monkeys, and we will soon begin a trial in human infants.

Accidental Injuries

Once infancy is past, injuries, not disease, become the leading cause of death and disability. Preventive approaches involve both pediatrics and the behavioral sciences. For example, studies we supported have developed and demonstrated the effectiveness of pediatric office-based interventions to have parents use car seats and seat belts for their children, and lower their home hot water heater settings to prevent scalding. To expand this research, last year NICHD solicited research grant applications on behavioral approaches to injury prevention. We have just begun awarding grants responding to that request.

Population Research

To address developmental problems that appear later in the life cycle, the NICHD supports a comprehensive research program in the population sciences. Goals of this program include devising improved treatments for infertility, and developing safe, effective, alternative methods of family planning. Despite the array of currently available methods, half of the six million pregnancies in the United States each year are unintended, so the need for new contraceptive methods and for understanding people's behavior in risking unwanted pregnancy is evident.

Contraceptive Development

Last year, in testimony before this Committee, the NICHD outlined plans for an increased research program in contraceptive development. Part of that plan included identification of natural products that could be used as contraceptives. I am pleased to report a major achievement in that effort. NICHD-supported scientists have isolated and characterized a protein called inhibin that appears to block a hormonal step necessary for the development of sperm and egg cells. Because inhibin does this without upsetting the body's hormone balance, it may lead to improved contraception for both women and men, and help us to understand some causes of infertility as well. We are also continuing studies of various brain hormones and immunologic aspects of reproduction that have implications for both contraception and infertility.

Unintended Pregnancy

The fact that over half of all pregnancies are unintended despite the availability of effective contraceptives emphasizes the importance of behavioral studies in addressing this problem. A large proportion of the Nation's unintended pregnancies occur among teenagers. NICHD research includes social and behavioral studies focused on factors that may lead to early childbearing. These include studies on initiation of sexual activity and starting and continuing contraceptive use. Several Institute-supported studies have examined factors differentiating sexually active adolescents who regularly use contraceptives from those who do not. Understanding how teens make decisions regarding sexual activity and contraceptive use can provide the basis for developing intervention programs to reduce the number of teenagers who become premature parents.

Contraceptive Evaluation

Over the past year, NICHD-supported researchers have reported major findings about three leading methods of family planning. First, young women who have used oral contraceptives are at no greater risk of developing breast cancer before menopause than are women who have never used them. Coupled with our earlier findings of an apparent protective effect of the pill against some reproductive system cancers, this provides valuable reassurance for the 70 percent of women who have used oral contraceptives at some time during their reproductive years. Second, women who have used IUDs are more likely than other women to become infertile, although the copper-bearing devices most commonly used today are least likely to cause such problems. Third, women who use contraceptive spermicides and unintentionally become pregnant have no greater chance of producing a premature or low-birth-weight infant or an infant with a birth defect than do women who become pregnant while using other types of contraceptives. The link between this program and our research in maternal and child health is readily apparent.

Mr. Chairman, the scientists we support are working in laboratories and clinics around this country on all these problems to bring about the day when our children's futures will truly be limited not by birth defects, mental handicap, or acquired illness and disability, but only by their dreams. With your continued support, we move every year closer to that goal.

The NICHD budget request for FY 1987 is $309,119,000. I will be glad to answer any questions you have.

Biography of Dr. Duane Alexander

BIRTH	August 11, 1940, Baltimore, Maryland
MARITAL STATUS	Married Marianne Ellis, Washington D.C., June 23, 1963; two children
EDUCATION	Pennsylvania State University, University Park, Pennsylvania, B.S. Degree, Pre-Medical, 1962 Johns Hopkins University School of Medicine, Baltimore, Maryland, M.D. Degree, 1966
INTERNSHIP	Intern and Fellow, Department of Pediatrics, Harriet Lane Service, Johns Hopkins Hospital, 1966-1967
RESIDENCY	Assistant Resident and Fellow, Department of Pediatrics, Harriet Lane Service, Johns Hopkins Hospital, 1967-1968
MILITARY SERVICE	1968-1970: Surgeon (LCDR), U.S. Public Health Service, and Clinical Associate, Children's Diagnostic and Study Branch, National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, Maryland 1971-Present: From Surgeon to Medical Director, U.S. Public Health Service
FELLOWSHIP	Fellow in Pediatrics (Developmental Disabilities), John F. Kennedy Institute for Habilitation of the Mentally and Physically Handicapped Child, Johns Hopkins Hospital, 1970-71
LICENSURE	Maryland Board of Medical Examiners
CERTIFICATION	Diplomate, American Board of Pediatrics, 1973
POSITIONS HELD	
1971-74	Assistant to the Scientific Director, National Institute of Child Health and Human Development, National Institutes of Health
1974-78	Medical Officer (Staff), National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, DHEW
1978-82	Assistant to the Director, National Institute of Child Health and Human Development, National Institutes of Health
1982-86	Deputy Director, National Institute of Child Health and Human Development, National Institutes of Health
1985-86	Acting Director, National Institute of Child and Human Development, National Institutes of Health
1986-	Director, National Institute of Child Health and Human Development, National Institutes of Health

AIDS

Senator WEICKER. Let me run through a few of the things that, obviously, occur to me. We have discussed AIDS here this morning. We do have young people being infected, somehow acquiring the disease. Would you like to comment on whatever your efforts are?

Are you involved in the AIDS effort in any way by virtue of that aspect of it?

Dr. ALEXANDER. We have become involved in the AIDS effort recently. Our epidemiologists, primarily, are working with their counterparts in the National Cancer Institute to develop studies on transmission of AIDS from mother to child, congenital AIDS, and the effect of congenital AIDS on the infant.

We also are interested in studying the neurologic impact for those who have the virus, but may not be showing any symptoms of disease. In another area, we are working to develop trials to look at the effects of spermicides and other barrier contraceptives as a means of preventing transmission of AIDS.

Senator WEICKER. My staff tells me that there are 246 cases of children with AIDs, and there have been 149 deaths as of February 10, 1986. These children are they mainly newborn, or what age bracket, and how do they get it, outside of what we normally know is the transmission of AIDS. What is the main reason for it?

Dr. ALEXANDER. We are aware of several methods of transmission. Most of the affected children have acquired AIDS in the newborn period, either congenitally from the mother who may be a drug addict who has AIDS and passes it to her fetus. Other children have acquired it from blood transfusions that are frequently given to premature infants, or from blood used in the course of their treatment for hemophilia.

Senator WEICKER. I notice, in the newspaper, where some of the older children are, obviously, having a difficult time, specially vis-a-vis their schooling. Is there any reason that you know, a medical reason, that these children are a danger to their classmates or not?

Dr. ALEXANDER. All of the information from the studies that have been done indicates that AIDS is not transmitted through casual contact such as would occur in a school classroom.

ADOLESCENT SUICIDE

Senator WEICKER. Adolescent suicides, is that something you are into, because it seems to me that this is very definitely on the rise, having almost tripled in the rate since 1958 as far as children between 15 and 19? Is this an area that has drawn your attention?

Dr. ALEXANDER. No, Senator; that is an area that falls within the province of the National Institute of Mental Health.

LOW BIRTH WEIGHT INITIATIVE

Senator WEICKER. This low birth weight situation, what initiative is it that you are starting here in 1 month's time, what is going to happen?

Dr. ALEXANDER. We are funding two sets of research networks that have been established across the Nation. We will be funding seven maternal-fetal medicine units in obstetrics departments and seven neonatal intensive care units. The purpose of these is to establish networks for the conduct of clinical trials in obstetrics and neonatalogy, with focus on prevention of low birth weight.

Senator WEICKER. Where are these located?

Dr. ALEXANDER. In obstetric and pediatric departments around the country.

Senator WEICKER. Are these located, in other words, in areas that have a problem?

Dr. ALEXANDER. Many of them are located in areas that have a high incidence of low birth weight. The units are all in medical schools or in academic institutions. One of the bases for their selection was the population that they have at risk for low birth weight, the number of patients that they serve, and the quality of the investigative staff available to design and participate in clinical trials.

The trials are not yet set up. The mechanism that we are using with them is a cooperative agreement where the investigators will work with NICHD staff in selecting topics for clinical trials, designing the protocols, and implementing them at each of their centers.

By combining seven centers, all using the same protocols, we can rapidly acquire the number of patients that we need for these studies, so that we can get answers relatively quickly. We can conduct several clinical trials at the same time among the same population. We also can make these networks available to other NIH Institutes for other kinds of studies that fall within their domain. The networks can provide a useful system for addressing those questions.

COORDINATION WITH DR. NICKENS

Senator WEICKER. Will you be working with Dr. Nickens, was that the gentleman's name, or will he be working with you in that?

Dr. ALEXANDER. We have been involved with the low birth weight area of the Secretary's task force on black and minority health. A member of our Institute chaired the subpanel on low birth weight and infant mortality. We plan to follow the recommendations of that group in some of the topics that we will be addressing in research in these networks.

NICHD FISCAL YEAR 1987 BUDGET CHRONOLOGY

Senator WEICKER. It seems to me that Dr. Nickens ought to meet Dr. Alexander if that is what he is supposed to be doing out of the Secretary's Office. It seems to me that we ought to have some sort of coordination in that.

Tell me about your budget, dollarwise and centswise, what was the original amount that you requested for your Institute?

Dr. ALEXANDER. The initial request of the Institute to the NIH was $374,148,000. The Department's request to OMB was $360,505,000.

Senator WEICKER. What was OMB's?

Dr. ALEXANDER. The President's budget is $309,119,000.

IMPACT OF BUDGET REDUCTIONS

Senator WEICKER. Children lost $65 million somewhere along the line. What were the principal areas of reduction?

Dr. ALEXANDER. They came across most areas of the Institute's programs, Mr. Chairman. The area of low birth weight lost a substantial amount, as did the contraceptive development initiative. Our proposed clinical trials in contraceptive development and low birth weight were affected.

Senator WEICKER. Have these clinical trials been temporarily postponed, the clinical trials in low birth weight?

Dr. ALEXANDER. Yes, sir.

Senator WEICKER. You were zeroed out on that one?

Dr. ALEXANDER. We are not zeroed out. We will initiate fewer clinical trials in those networks than we had planned.

Dr. WYNGAARDEN. Senator Weicker, perhaps I should point out that the specifications from OMB dealt with the number of awards and the amount of money in the research project grant category. Many of the specific impacts that flowed from the dollar value represented decisions taken by individual Institutes.

Senator WEICKER. I understand that. I appreciate that comment, but once you have set certain parameters, other results are certain to flow, and there you have it.

I have further questions that I am going to have you respond to for the record, Dr. Alexander. But I can't think of anything that makes this situation clearer than what we are talking about right here, just in this Institute, which is a small institute.

There is nobody in this Nation that wouldn't agree that our most precious resource are our children. Here we have about a 20-percent cut in your Institute.

Dr. ALEXANDER. Yes, sir.

Senator WEICKER. I don't think that this is anything for anybody to show as a matter of pride. I am not talking about you, and I am not talking about the National Institutes of Health, I am talking about the Nation.

Does the national debate feel that we want to apply a 20-percent cut to the children of this country? I can't believe it. I just can't believe it. We have seen it in many other forms, but let's let everybody understand what is going on here, especially in some of the areas that you have described.

I do appreciate your testimony. As I said, we are under some time constraints right now. There will be further questions for response to the record. I can assure you that I am going to be pretty darn close and that those moneys are going to be restored to many of the Institutes at NIH.

This is a good, graphic lesson in what this budget is all about. I can't think of a better one.

Jim, various directors, and personnel, I thank you all for your patience over the past several days. We will be working closely with you in shaping our budget. Hopefully, we will be able to make some sense out of some of the cuts. I can also assure you, Jim, that we will be paying close attention to some of the internal matters of structure at NIH.

It is a little hard, once I get the ball rolling out there on grants, which is the most visible one, to slow that one down. The people have to go through a learning process, the same as I do as to what is going on here, but let's see if we can sort of bolster things up in some of these other areas.

Thank you all very much.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

LOW BIRTH WEIGHT RESEARCH

Question. What has happened in the area of low birth weight research?

Answer. In FY 1985, the NICHD began implementing an enhanced research program focused on the prevention of low birth weight (LBW) and infant mortality, the most important problems in maternal and child health in the United States today. LBW infants often require long periods of costly intensive care and have high mortality and morbidity. LBW may be due to intrauterine growth retardation (IUGR), premature labor, or both. The impact of LBW on society is profound. Two-thirds of all infant deaths occur among LBW infants, and many of the surviving infants have lifelong physical or mental handicaps. The poor U.S. international ranking in infant mortality is due almost entirely to our higher rate of LBW.

In FY 1985 two new perinatal research centers were funded with a focus on identifying the causes of LBW and developing interventions to prevent this problem. Currently under way is the vaginal infections and prematurity study. This is a large, randomized, controlled clinical trial in which women are screened for asymptomatic vaginal or urinary tract infections, thought to cause LBW, and treated with antibiotics in an attempt to prevent LBW. At this time, nearly half of the more than 15,000 women to be screened have been recruited. In addition, NICHD scientists have helped design and initiate a study of prevention of LBW in the District of Columbia, the Better Babies Project.

Question. How much did you spend on this research initiative in FY 1985, and how much will you spend in FY 1986?

Answer. NICHD funding of research on infant mortality and LBW was $37.8 million in FY 1985. The estimate for FY 1986 is also $37.8 million.

Question. What will be the impact of the President's budget cuts on this research initiative?

Answer. The President's budget for FY 1987 provides $38.8 million for the NICHD in the area of low birth weight and infant mortality, an increase of $1.0 million over the FY 1986 revised level.

Question. What will the real impact be in terms of treatment for women with high risk pregnancies, and for their babies?

Answer. Research on high risk pregnancy is basic to the understanding of LBW. The budget for FY 1987 provides sufficient support to continue ongoing projects and will permit further development of the two center grants that began in FY 1986. The newly established cooperative network of maternal-fetal research units will start multi-center clinical trials in FY 1987 on controversial management questions in high risk pregnancies. In the program on initiation of labor and prevention of prematurity, the multi-center contract "Prevention of Prematurity by Detection and Treatment of Gestational Genitourinary Infections" will also

continue gathering important and pertinent data regarding the problem of LBW.

LOW BIRTH WEIGHT STUDY IN THE DISTRICT OF COLUMBIA

Question. I understand that NICHD has been supporting a study of low birth weight babies in the District. Some areas in this city have reported a 15 percent incidence of low birth weight babies--more than double the national average. What has been the impact of this project?

Answer. The study of low birth weight babies in the District of Columbia, the Better Babies Project, represents a collaborative effort involving the Greater Washington Research Center, the District of Columbia Government, and the National Institutes of Health. The purpose of the project is to determine whether outreach to identify women early in their pregnancy, and link them to existing medical and social services, can reduce the high incidence of low birth weight. Since a high rate of participation will be required to assess impact, we are currently in the process of attempting to improve methods of outreach to insure participation of up to 75 percent of the pregnant women living in the target area. In addition, we are completing development of the protocol and pretesting various interventions. While experience has been encouraging, data are incomplete at this time. A decision on whether to continue this project beyond the pilot phase is expected by June of this year. It will then require an additional 3 1/2 to 4 years to obtain sufficient numbers of participants to measure the impact of the project on the rate of low birth weight in the target area.

Question. Will you be able to continue providing the necessary funding to keep it going?

Answer. Funding for the Better Babies Project comes primarily from private sources. Thus, should this project continue beyond the pilot phase, additional funds must be raised from private foundations. NICHD is providing staff assistance in direction of the study and will provide funds for data collection and analysis, including evaluation of the impact of the project on the target population.

RESEARCH IN MENTAL RETARDATION

Question. I understand that there are many causes of mental retardation. For example, I know that the identification of a metabolic defect called PKU prevents mental retardation by controlling the newborn infant's diet. How much money do you think we saved the taxpayer by this discovery?

Answer. It costs $13,000 to identify a newborn infant with PKU: it costs approximately one dollar to test each newborn, and the incidence of the PKU condition is 1 in 12,000; the cost to confirm a positive case in $1,000. To maintain a normal blood level of phenylalanine with a special diet containing restricted amounts of phenylalanine for a period of ten years will cost another $50,000 per patient. The net cost of identification and treatment is thus approximately $63,000. Before the newborn screening programs for

PKU were initiated in the mid 1960's, children with PKU almost invariably became severely to moderately mentally retarded and required life-long institutional care. Fifty percent of these children survive to 33 years of age when institutionalized under age 6 and an equal proportion, i.e., 50 percent, live over 50 years when admitted at an older age. In 1984 the national average daily expenditure per patient in state-supported institutions for the mentally retarded was $106. Conservatively, it is estimated that the lifetime cost of institutional care for each case would be some $1.3 million, and without the diagnosis and treatment, there would have been an additional 250 cases of mental retardation from PKU annually. Excluding the costs to society due to reduced productive activity among the mentally retarded, which was estimated to be $4.8 billion in 1970, it is clearly evident that early diagnosis and dietary management of PKU is cost-effective.

Question. Are there other causes of retardation that can now be prevented or cured?

Answer. Research advances have resulted in remarkable progress in the prevention of mental retardation. Preventable inborn errors of metabolism that are associated with brain damage other than PKU (250 cases per year) include congenital hypothyroidism (1,000 cases per year), galactosemia, maple syrup urine disease, and abnormalities of urea cycle enzymes resulting in elevated levels of blood ammonia. Before the live measles vaccines became available in 1963, this common childhood disease occurred at an annual rate of four million cases in the United States. This led to 4,000 cases of encephalitis, 1,300 cases of mental retardation, and 400 deaths. Vaccination programs against measles have dramatically reduced the mortality and morbidity associated with this infection, and virtually eliminated it as a cause of mental retardation. Rubella, or German measles, during pregnancy is another infectious disease which can cause mental retardation, deafness, blindness, and other serious handicaps when it infects the unborn baby. In the worst rubella epidemic, in 1963-1964, 20,000 to 30,000 children were born with congenital rubella. With the introduction of rubella vaccine in 1968, the incidence of rubella has declined precipitously, and congenital rubella syndrome has almost been eliminated. The prevention of Rh hemolytic disease of the newborn, due to blood incompatibility between the mother and the fetus, became possible in 1968 with the licensing of Rh immune globulin, and mental retardation, cerebral palsy, and deafness due to this condition have nearly disappeared. Mental retardation and brain damage associated with lead poisoning has also declined in frequency due to the institution of public health measures which decreased the risk of exposure of children to lead.

Question. Where will you look next for the still unknown causes and for new methods of prevention and cure?

Answer. Basic and clinical research on normal and abnormal brain development and the causes of mental retardation will contribute significantly to our understanding of developmental disabilities. Newborn screening programs for inborn errors of metabolism need to be expanded. Animal models for genetic disorders are necessary for a better understanding of the basic mechanisms which result in developmental disorders. Replacement of missing or

abnormal enzymes, cloning of genes with a long-range objective of replacing absent or defective genes, and reduction in the incidence of premature births are but a few of the methods that can result in the prevention or cure of certain types of mental retardation.

The advance with the most immediate promise for eliminating a major cause of mental retardation is the vaccine for Hemophilus influenzae infections in infancy that has been developed in the NICHD intramural program. This vaccine is just entering clinical trials, and if effective, can eliminate the current leading cause of acquired mental retardation in the United States (3,000 to 5,000 cases per year).

MENTAL RETARDATION RESEARCH CENTERS

Question. I understand that you are now supporting 12 mental retardation research centers. Is that correct?

Answer. That is correct. The NICHD currently supports 12 Mental Retardation Research Centers (MRRCs).

Question. What activities in addition to research do these centers support?

Answer. The centers support research training, translate new research knowledge into application, disseminate research information, and provide scientific and diagnostic resources serving the states and regions in which they are located.

Question. I note that you are not planning to reduce the number of centers supported by your institute. If the President's budget cuts become reality, what percentage of funding will these centers lose?

Answer. Funding for the 12 MRRCs is estimated at $8.9 million in FY 1987, approximately 16 percent below the estimated full-cost level of $10.6 million.

Question. What portion of their program will absorb these cuts?

Answer. The MRRC program will absorb these cuts by reducing selected, lower-priority scientific activities, including postponement of plans to use the centers as a network for collaborative clinical trials in prevention or amelioration of mental retardation.

BIRTH DEFECTS

Question. You have indicated that expanded research opportunities exist in the area of birth defects and genetic diseases. What are some of these opportunities?

Answer. Improved cell cultures, ability to produce monoclonal antibodies with exacting specificity, and availability of recombinant DNA methodology have all provided unique new approaches to understanding genetic diseases. Recombinant DNA technology especially provides novel opportunities in human genetics. This

allows an improved means of mapping genes to the human chromosomes and identification of markers for genetic disease for use in diagnosis and counseling. New insight into the molecular and biochemical causes of hereditary disease will be possible through identification of the disease gene, and through study of how the disease gene functions in an abnormal way.

Question. In your professional judgment, what research opportunities will have to be put on the back burner because of an inadequate budget?

Answer. The research field of genetics is burgeoning with new ideas and approaches for furthering our knowledge of human genetic diseases because of this new technology. It is important to identify the genes responsible for disease. This will require sequencing of the entire human genome, understanding its organization and discovering its genetic controls. Knowledge of the genome and availability of probes for important genes is crucial. This takes manpower and research support. The technology is there although improvements are required to shorten the time required. To further assist in attaining this goal, the NICHD has just begun to fund a repository of human DNA probes and libraries as a research resource for the scientific community. The goal of this DNA repository is to provide to investigators the highest quality molecular probes available, eventually representing the entire genome. The most useful and best characterized probes have been identified and are being donated to this collection by the researchers who constructed them. The repository is expected to process approximately 200 probes each year. This rate of accession will fall behind the rate of new probe development (currently, approximately 1,000 probes qualify for the repository and the number of new probes developed has been doubling each year).

Question. Can you identify a birth defect or genetic disease and project its yearly cost to the economy and then tell us how much is being spent on research on this disease?

Answer. We have no currently available estimates on total yearly costs to the economy for a specific genetic disease. We can approach the yearly cost to the economy by examining just one component--the annual cost of institutionalization of the mentally retarded. In 1981 the President's Committee on Mental Retardation estimated these costs to be $1 billion dollars a year. If we apply a conservative inflation factor of 5% to this figure we compute a current cost to the nation of $1.3 billion. A major portion of the patients institutionalized for mental retardation are retarded due to a birth defect or genetic etiology. Of course this is only a portion of the cost and does not include the lost productivity that results from handicaps that attend birth defects and genetic disease and the social service costs of those citizens that are not institutionalized but are in need of various forms of social support. However, we can point out important new research advances such as the use of the presence or absence of a restriction site in DNA allowing it to be used as a marker for the diagnosis of human genetic disease. At the present time these DNA probes have been used to diagnose sickle-cell anemia, thalassemias, Lesch-Nyhan syndrome, phenylketonuria, Duchenne-type muscular dystrophy, glucose-6-phosphate dehydrogen deficiency, and adenosine deaminase

deficiency. Recently DNA probes have also been informative for Huntington's disease, cystic fibrosis, and ornithine carbamoyl transferase deficiency. These probes have provided the first clues in finding the defective genes. DNA probes are already used for prenatal diagnosis of sickle-cell anemia as well as phenylketonuria which causes severe mental retardation if not treated. The same potential exists in the study of other inherited diseases which are not yet fully understood or susceptible to diagnosis and treatment. It is also important to point out that as high as 30% of patients admitted to some pediatric hospitals suffer from a genetic disorder or a congenital malformation.

Question. In your professional judgment, how much should be spent on research for this disease?

Answer. I believe that $37.5 million is the appropriate level for the FY 1987 NICHD effort in research on birth defects.

CONTRACEPTIVE RESEARCH AND THE PRIVATE SECTOR

Question. I would think that the profit that would result from the development of a better contraceptive would be a major stimulus for the private sector to support research of this kind. Can you estimate what kind of research effort is going on in the pharmaceutical industry in this area?

Answer. Through the decade of the 1960s the American pharmaceutical industry was very active in contraception research. All of the oral contraceptives and some of the IUDs were developed as the result of industrial activity. Starting in the mid-seventies, industrial investment in contraceptive research has been substantially reduced. The triphasic oral contraceptives that have become available during the past 3 years are essentially a reformulation of existing products. Currently in the U.S. there is only one pharmaceutical company that is actively pursuing the area of contraceptive research with its own resources.

Question. Why is the federal government supporting contraceptive research when so much of this research is being done in the private sector?

Answer. The reason for the involvement of the Federal Government in supporting contraceptive research is that the private sector has, to a large degree, withdrawn from this area. The costs incurred in defending numerous law suits and the loss of product liability insurance have been listed as primary factors for the current situation. The bulk of contraceptive research is supported by NICHD and the U.S. Agency for International Development.

CONTRACEPTIVES - RESEARCH EFFORT VS. BUDGET

Question. How much effort is your Institute making in research on new and improved methods of contraception?

Answer. The NICHD is exerting a considerable effort to develop new and improved methods of contraception. Last year the Institute proposed a special contraceptive development initiative in recognition of the needs for better methods of fertility

regulation. This initiative is being carried out within the limits of the regular NICHD budget.

Question. Can you tell us if anything new is on the horizon?

Answer. We can anticipate that within the next several years there will appear several new barrier methods. We are actively supporting research on new long-acting injectables and implants. This research has reached clinical stages. Research on male methods of fertility regulation is actively pursued, even though advances have been slow in coming. On the more distant horizon is the exploration of naturally occurring reproductive inhibitors, such as inhibin, and the development of anti-fertility vaccines.

Question. Given the obvious need for research in this area, will the proposed FY 1987 budget allow you to continue to pursue this research aggressively, or are there particular research opportunities that will be missed because of the lack of necessary funds?

Answer. The proposed FY 1987 budget will permit us to pursue contraceptive research at a stable level. More advanced projects, such as for barrier contraceptives and long-acting injectables, will receive support for continuation. Less advanced projects will proceed somewhat slower. Among the areas that require stimulation are immunocontraception, naturally occurring reproductive inhibitors, and the exploration and synthesis of new drugs for male fertility regulation.

SUDDEN INFANT DEATH SYNDROME (SIDS)

Question. How much is your Institute spending on Sudden Infant Death Syndrome Research?

Answer. NICHD funding in Sudden Infant Death Syndrome (SIDS) research was $19,044,000 in FY 1985, and estimates for FY 1986 and FY 1987 are $18,800,000 and $18,900,000, respectively. These amounts include funding for projects related specifically to SIDS, as well as for those generally related. The amounts included above for only specific SIDS research are $1,133,000 in FY 1985, and $1,100,000 estimated each year for FY 1986 and FY 1987.

Question. Are we getting any closer to understanding this condition?

Answer. The best answer to this question is that we are getting closer to understanding what SIDS is not. The cause or causes of SIDS remain unknown, but ongoing research has delineated the normal development of respiratory, cardiac, and neurophysiological functions in normal infants and those at risk for SIDS. It has been recognized that SIDS victims often are not as normal as they were once thought to be, but it is not yet possible to identify prospectively potential victims. The difficulty in achieving this goal results from the recognition that SIDS may have multiple causes, and research efforts are directed toward their elucidation.

Question. In your professional judgment, how much more should be spent on research in this area?

Answer. In my professional judgment, an additional $4,000,000 should be spent in FY 1987 for SIDS research. Of this amount, $800,000 would be for specific SIDS research, and $3,200,000 would be for research in high-risk infancy and high-risk pregnancy generally related to SIDS.

INJURY RESEARCH

Question. Last year this committee encouraged you to place special emphasis on the area of accidental injuries in children. What has been the response to your special solicitation for grants in this area?

Answer. In response to the NICHD special Request for Applications in the area of childhood injury, 50 proposals were received. Of these, 26 were approved, and it is expected that one will be funded in FY 1986.

Question. In your professional judgment, how much more should be spent on this area of research?

Answer. At the present time, it is a lack of quality proposals that precludes additional research in this area, more than insufficient funds. The Institute plans to work with the scientific community to improve the research methodology in this field and stimulate additional research.

CHILDHOOD IMMUNIZATION - VACCINE RESEARCH

Question. The importance of this country's program of childhood immunization cannot be stressed enough. I am concerned, however, that vaccine development and research is not receiving a high enough priority. How much effort is being made to develop new vaccines in light of the new genetic technologies?

Answer. Investigators are now using approaches to define precisely the molecular and cellular mechanisms for specific immune recognition and immune response in humans, and to establish their relevance in host defense against specific organisms. This includes isolating and characterizing the major immunogenic proteins of the infectious organisms as well as the genes encoding these proteins. The nature of the specific immune response is also evaluated for its relationship to the specific organism. There is also a special effort to focus on the immune responses in infants, since this is frequently the time when vaccines are administered, and infants can respond differently than adults with certain vaccines.

Much effort is also being devoted to developing new vaccines within the NICHD Intramural Research Program, especially vaccines directed against common, serious bacterial infections of infants and children. The step-wise approach that we are taking is to develop new vaccines based upon single highly purified and easily standardized components of bacterial organisms and to demonstrate the efficacy of these vaccines. Once we have demonstrated safety and efficacy, it will be an easy matter to identify and clone the

genes which encode these products, and quickly produce a generation of new vaccines using recombinant DNA techniques.

Question. Are any new vaccines on the horizon?

Answer. Yes, there is considerable activity in this area. One example in the extramural program involves a cytomegalovirus (CMV) vaccine. The Towne cytomegalovirus vaccine has been studied in renal transplant recipients and normal volunteers, and the intent is to extend trials with this vaccine into larger numbers of normal humans who are considered at high risk for acquiring CMV. CMV is a common virus that is harmless to most people but poses the greatest risk to developing fetuses, in some cases causing mental retardation and physical disabilities.

Within the Intramural Program, we are currently developing seven new bacterial vaccines: (1) A protein-sugar vaccine directed toward Hemophilus influenzae (H. flu) that would be effective in infants. The recently licensed H. flu vaccine, based upon our earlier research, is adequate for older children but does not elicit immunity in infants--who are at the greatest risk for morbidity and mortality from this organism. H. flu causes severe respiratory infections, which can be fatal, and meningitis, which can end in mental retardation. (2) A vaccine against pneumococcal pneumonia that would be effective in infants and young children. The current vaccine is effective in adults, but not in the young nor the immunologically compromised. (3) A vaccine against meningococcal meningitis. Again, the current vaccine against this organism is not effective in very young children nor in the immunologically compromised. (4) A new vaccine against the organism of typhoid fever, which still occurs in millions of people, especially in third-world countries. The current vaccine causes many side effects, and is effective for only a short time. Our new typhoid vaccine is currently in clinical trial in Nepal. (5) A vaccine against Staphylococcus, a common cause of severe skin infectons and occasionally, life-threatening systemic infections. (6) A vaccine against certain bacteria which have been associated with a form of arthritis, ankylosing spondylitis. (7) A new vaccine against pertussis.

Question. What is the status of your intramural research program on a safer and more effective pertussis vaccine?

Answer. The new pertussis vaccine developed in the Intramural Research Program will be assessed in adult volunteers at the NIH Clinical Center next month, and in adults and children this summer in a large field trial in Sweden. We are also planning a major trial in the United States involving the entire State of Massachusetts. The new vaccine is based upon a single component of the pertussis organism, pertussis toxin. Interestingly, while this is the component that causes the symptoms of whooping cough, it also appears to induce immunity to the infection. The inactivated, highly purified toxin should produce many fewer side effects than the existing vaccine which is an impure, poorly standardized mixture of many pertussis components--most of which seem to be unnecessary for an effective vaccine. Moreover, the structure of a single pure component can be analyzed and controlled by the very latest chemical and physical techniques, insuring that our vaccine will remain

absolutely stable, predictable and safe. It will require about three years of extensive clinical trials before we have sufficient information to insure an entirely safe and effective vaccine, followed by FDA approval and commercial production. Just to prove efficacy would require very little time, but since the most serious side effects of the existing pertussis vaccine are rare, we will have to give the new vaccine to many thousands of children before we can be sure that the rare incidence of serious side effects has been significantly reduced.

INTRAMURAL RESEARCH/QUALITY VS. BUDGET

Question. You have described the many new accomplishments produced by the research scientists in your Institute's intramural program. Yet I have heard a few comments expressing concern that the intramural research program at NIH has not received the same support and attention as the extramural program. In your professional judgment what is the status of the intramural research program in your Institute, and what can be done to improve it?

Answer. The status of the Intramural Research Program in our Institute is very strong at the moment. We are blessed with a group of exceptionally motivated and creative scientists working with relatively limited resources in the very broad area of human development. This year, our Intramural Research Program published almost three times as many scientific reports as was the case five years ago. Their research is directed not only toward preventing birth defects and mental retardation, but they are addressing developmental problems that set the stage for the later occurrence of cancer, hypertension and heart disease, immunological diseases, premature aging, and behavioral disorders.

The opportunities in this area of research have never been greater, thanks to the availability of recombinant DNA, monoclonal antibody, and other new biological techniques that have moved us forward by leaps. Research in this field is being revolutionized by the fact that we can now manipulate organisms at the level of their genes, that is, we can easily insert new genes into cells, or we can remove the function of normal genes selectively. This approach is permitting us to understand, with a rapidity that was unimaginable just five years ago, exactly how the expression of genes is controlled from the moment of fertilization onward throughout life. Not only is this research already of unprecedented benefit with respect to our knowledge of how the fundamental life processes work, but it is paving the way for the prevention and treatment of common, life-threatening diseases by "gene therapy."

Two kinds of resources are needed to improve the Intramural Research Program. First, increased operating funds and a higher employment ceiling would provide additional staff, state-of-the-art high technology equipment to replace outmoded equipment, and scientific supplies and support services in greater quantity than are available now. Next, we still look toward construction of an NICHD intramural research building, although in a modified version of the plan we have described to the Committee previously. Now we are working on a design that would not only consolidate the NICHD intramural program, but would also serve to bring together the intramural neuroscience programs and related primate facilities of other institutes that do comparable research.

Question. Will the scientists in the intramural program be affected by the proposed budget cuts in the same way as their counterparts at universities?

Answer. Intramural scientists would be affected by the proposed budget cuts, although not in the same way as their counterparts at universities. While it is true that the funding of the intramural program provides stability and continuity and that there will be at least some federal funds available (unlike the situation when an NIH grantee fails to receive an award), it is also true that our counterparts at the universities may receive funding from multiple sources, including foundations, state legislatures, endowments, and corporate as well as private donations. Intramural scientists, just as extramural investigators, face curtailing the scope of their research by using fewer supplies, postponing equipment orders, studying fewer patients, and operating with fewer support personnel as a consequence of their reduced budgets.

IMPACT OF BUDGET REDUCTION

Question. The President's budget proposal for FY 1987 reduces your budget by $12,677,000 under FY 1986 appropriated levels. Gramm-Rudman-Hollings, if triggered, could reduce your budget even further--maybe by as much as 20 percent. I've known this would reduce the number of grants, possibly the size of grants, Centers, training, etc., etc. Can you give us some idea of the impact of these reductions on the kinds of research that would be stopped or lost?

Answer. In FY 1986, reductions resulting from Congressional implementation of the Balanced Budget and Emergency Deficit Control Act of 1985 were applied equally across all programs and activities of the NICHD. It is anticipated that future fiscal years' reductions under this Act would be applied in a similar manner. Most likely, some research would have to be stopped or lost, because there is a limit as to how much research can be reduced in scope before elimination of certain projects is necessary.

Question. What impact might this have on the health of our citizens five and ten years down the road?

Answer. The significant reductions to which you refer would certainly limit our ability to sustain the research base and pursue new avenues of research. It is impossible at this time to project precisely the impact of these reductions on our citizens five to ten years from now.

Question. Can you discuss your contingency plans if these massive budget cuts should come to pass?

Answer. Currently, there are no contingency plans for such budget cuts in FY 1987.

Question. If the automatic provisions of Gramm-Rudman-Hollings are triggered in FY 1987, your Institute may well have its budget reduced by 20-25%. Have you prepared a contingency plan in the event Gramm-Rudman-Hollings becomes reality? If so, please send a copy of your plans to this committee.

Answer. No, the NICHD has not prepared a contingency plan for further reductions in FY 1987. Rather, the FY 1987 budget was developed to meet deficit targets of the Gramm-Rudman-Hollings Act.

Question. If cuts of this magnitude become reality, how will they be distributed: Intramural vs. extramural programs; peer review system; would number of site visits be reduced? Would travel to NIH to study section meetings be affected? Would NIH employees have to be furloughed? What major programs would have to be cut back?

Answer. Budget reductions of this magnitude would have to be applied to both intramural and extramural programs, as well as to all our administrative and operating activities. The nature and extent of cuts in specific areas such as peer review functions and NIH employment would depend on the relationship between these administrative components and research programs of the Institute. We would expect that all major programs would have to absorb at least some cuts.

Question. Please list the research programs of the highest priority that should not be cut and why.

Answer. With cuts at the level of 20-25%, it is unlikely that any programs could be spared from reductions.

Questions Submitted by Senator William Proxmire

TEENAGE PREGNANCY

Question. On page 90 of your justifications you point to a study assessing the effects of teen parenthood on the offspring's school-related achievements. The study found that the most important predictor of the child's academic progress was the mother's own educational attainment. Frankly this seems to be close to a self-evident conclusion. Has there ever been a study that found the educational attainment of the parents was <u>not</u> an important factor in a child's academic progress?

Answer. A major area of interest in regard to teen pregnancy and childbearing has been the effect on the children born to teens. Does teen childbearing not only disadvantage the young woman, but also her children? Not surprisingly, the answer is yes, but the answer is more complicated than a simple answer would suggest. Teen mothers are different from older mothers in ways other than age, such as income and their education. When you take these other differences into account the difference between the achievements of the children of teen and older mothers is lessened. This means that much of the effect of being a teen mother is channeled through social and economic conditions. The reason the children of teen mothers do less well in school performance is less because they are born to a woman of a given age and more because they are born to a woman with poor education herself. Even though the teenager may have had poor prospects to begin with, a birth reduces her educational chances even further. We know this hampers the young woman's opportunities in life, and it also echoes in the life chances of her children.

Recent research suggests that the educational level of the mother is an important factor in the relative well-being of the children of teen parents. Children of teen dropouts seem to do worse on measures of educational ability/achievement than do those children born to teens who were in school at the time of the birth. Most ameliorative programs seek to keep the pregnant girl in school. This is a challenge but we are seeing significant increases in the proportion of teen mothers who stay in school after a birth. However, the children at greatest risk may well be those born to young women who dropped out prior to the pregnancy. These may be the hardest to reach, but, given the effects on the children's education and concern about repeating these problems (school drop-out and teenage pregnancy) in future generations, the research finding is important for program and policy development.

AIDS RESEARCH

Question. Dr. Alexander, you point out in your detailed justifications that the AIDS virus may be transmitted from mother to child through breast-feeding. However, you apparently don't know whether or not this will confer AIDS immunity to infants receiving their mother's milk.

Are you trying to answer this question through your research program at the present time? If the AIDS problem becomes as widespread as many think, this may become a significant issue.

Answer. The question of AIDS transmission from mother to child through breast-feeding is being addressed as part of an epidemiological study initiated this fiscal year. This project involves a study of a high-risk group of pregnant women, with the primary goal to assess the rate and mode of HTLV-III/LAV transmission as well as the outcome of the children born to these women.

SUBCOMMITTEE RECESS

Senator WEICKER. The hearing will stand in recess until tomorrow morning, at 9:30, at which time we will hear from the Office of the Inspector General, the Office for Civil Rights, the Centers for Disease Control, and the Alcohol, Drug Abuse, and Mental Health Administration.

Thank you very much.

[Whereupon, at 12:57 p.m., Wednesday, March 12, the subcommittee was recessed, to reconvene at 9:30 a.m., Thursday, March 13.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1987

THURSDAY, MARCH 13, 1986

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10 a.m., in room SD-116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker, Specter, Proxmire, Chiles, Burdick, and Harkin.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE INSPECTOR GENERAL

STATEMENT OF RICHARD KUSSEROW, INSPECTOR GENERAL

OPENING REMARKS

Senator WEICKER. The committee will come to order. This morning we will complete our hearings on the administration's proposed fiscal year 1987 budget as well as the fiscal year 1986 rescission supplemental for the Department of Health and Human Services.

Today we will cover programs of the Centers for Disease Control, the Alcohol, Drug Abuse, and Mental Health Administration, and the Department's Office for Civil Rights, and the Office of the Inspector General. We will first hear testimony from Richard Kusserow, inspector general of Health and Human Services. Please make yourself comfortable, and your statement in its entirety will be included in the record. Please proceed in synopsizing in any way you consider fit.

SUMMARY STATEMENT

Mr. KUSSEROW. Thank you, Mr. Chairman. I am Richard Kusserow, the inspector general for the Department of Health and Human Services, and I would like to summarize my statement for you.

Since 1981, the Office of the Inspector General has been making efforts to fulfill its statutory mission to provide leadership, coordination, and recommendations to promote economy and efficiency in preventing

fraud and abuse in the Department's programs. As in preceding years, we are continuing to keep our efforts in line by proportioning our staff resources consistent with the major allocation of the Department's total budgetary outlays in areas of high vulnerability.

Consequently, Social Security, Medicare, and Medicaid, as well as the grants and internal financial systems, continue to consume the bulk of our audit, inspections, and investigative resources.

This redirection has in turn resulted in the continuous and progressive rise in prosecution sanctions as well as savings and recoveries for the Department's programs, and all of this has been done without real budgetary resource increases to our office over the last 5 years.

1985 was no exception, as indicated by the attached graphs. During that fiscal year we continued to practice our approach of improving Office of Inspector General management by increasing our efficiency and effectiveness. Our accomplishments, as illustrated in our semiannual report to the Congress, continue to exceed our earlier expectations.

During fiscal year 1985, over $4,900,000,000 in settlements, fines, restitutions, recoveries, and savings were realized for the Department's programs, thus supporting the upward trend. This represents a 3,000-percent increase in output by our office since 1981, with a return ratio of nearly $68 for each $1 spent to support our activities.

During the same time our investigative efforts rose from 165 convictions to over 1,005 convictions last year. This represented a 600-percent increase. We also obtained administrative sanctions against 390 health providers and suppliers by kicking out those individuals from the Medicare and Medicaid Programs who had engaged in fraud or abuse of the programs or the patients.

In 1987 we intend that a majority of our work will continue to be focused in the Medicare and Social Security Programs of our Department. From that, we think that we can continue to maintain our high productivity.

With that, Mr. Chairman, I will open up to any questions you might have about our operations.

SUSTAINING SAVINGS DURING STAFF CUTS

Senator HARKIN [presiding]. Thank you, Mr. Kusserow. I just have a few questions for the record.

Mr. Kusserow, your fiscal year 1987 budget request proposes 1,214 full-time equivalents, a reduction of 100 below the fiscal year 1985 level, yet you are still planning $5 billion in savings recommendations, almost the same dollar amount as in fiscal year 1985. How do you sustain savings outputs when you lose 100 auditors and investigators?

Mr. KUSSEROW. Well, in the long run, I don't know whether I could maintain the output. In the short run, we have a lag time from the time we initiate our work until a final action is taken, whether that be in the form of an investigation completed and going to prosecution in U.S. district court or whether it is an audit recommendation for disallowance that departmental management or Congress has to act upon or recommendation to effect a program change.

So a lot of it is the fact that this year the full effect of the cuts won't be felt on us as the pipeline continues. Next year will represent a more serious test of our ability to increase efficiency in moving ahead with productive outcomes.

So that is basically why I am not as concerned about this year—although I have some concerns. We are struggling much harder this year to maintain the same levels, but next year probably will be a more severe test for us.

Senator HARKIN. What you are saying is that you hope to have $5 billion in savings recommendations. But you are saying it is going to be tough to reach that with the reductions that you have.

Mr. KUSSEROW. I think we stand a reasonable chance of maintaining that goal for this year. It is next year I am not too sure how well we will do. I hope that we can still maintain those goals, but it is going to be a more severe test of our skills in being efficient to do that.

PROSPECTIVE PAYMENT SYSTEM

Senator HARKIN. Regarding the prospective payment system, what measures is your office taking to monitor the quality of health care under Medicare's prospective payment system for inpatients in hospitals?

Mr. KUSSEROW. Among the things we have been doing and will continue to do, is to monitor all of the reports of the peer review organizations, or PRO's. We are looking at them very closely to see that they are going to be a good watchdog for the quality of care issue in the hospital setting for the Medicare beneficiary.

We have also just completed fiscal audits of all of the PRO's to make sure they have sufficient resources to meet their contractual obligations to Medicare and their beneficiaries. We feel that we will continue to have to work in the area of reviewing the individual diagnostic related groups [DRG's]. The DRG's, or diagnostic related groups, are built upon a system of records that originally had been designed for morbidity and mortality purposes and were later adapted for fiscal reimbursement. There are fossilized problems within that. When you develop one set of data to be used for another purpose, there are going to be problems in there. So we are going to continue to monitor each of the DRG's to see if, in fact, there are inappropriate procedures or ways to procedures and make sure that they are put in the right category.

We are going to look very hard to see whether there are error rates in how the principal and secondary diagnoses of the admitting physicians are going to be coded by the medical records people and whether those error rates represent a threat on the Medicare system and whether we need to prepare some adjustments on it.

So we are going to be working on the whole area of the admissions and how they characterize the admissions, how they provide inpatient services, and what category of services they provide. We will also examine the discharge data from the hospital to be sure the quality of care won't slip under PPS.

EARLY DISCHARGES

Senator HARKIN. Do you do any followup work? In my State I get a lot of patients who have been released under the system, and a lot of the families feel that they have been released too soon, that they then are not fully recovered and they have to be readmitted or admitted someplace else, and the savings that may have accrued to the hospital from getting the patient out the front door in a specified length of time really is not much of a savings because it has got to be picked up someplace else because the person is not fully recovered yet.

So when you say you are checking discharges, that you go through the discharges, are you doing any kind of followup to see if there is any subsequent cost to the system of people who have been released early?

Mr. KUSSEROW. We are in the process of completing a report on that whole subject, and with your permission I will send it to your office when it is completed.

REASONS FOR EARLY DISCHARGES

Senator HARKIN. I hear a lot about that.

Mr. KUSSEROW. I think it is a thing that is causing a lot of concern among a lot of the beneficiaries. I think when we look at discharges we have to look at it as if a discharge is premature, what is the reason for the premature discharge? Was it because the patients decided to discharge themselves against the physician's advice? Was it an error? An isolated error in judgment by a physician? Or is it a situation where—and it sometimes does happen—that the medical community and the practitioners are not infallible?

Could it be that when they look at the records and where all reasonable physicians would agree that it would be appropriate for discharge, that somehow the human being involved doesn't cooperate and they have an unpredictable consequence which would require readmission?

Or is it that physicians feel pressured by the hospital system, to game the system in such a way by discharging people before they are ready to go home?

I think it is a combination of all of them. The question is as to what degree? Is it a question of the latter category, because that is a more serious one? If the patient goes against the physician's advice, that is their prerogative. They are not a prisoner of the hospital.

But if on the other hand a physician is feeling the pressure of a hospital system, or they are incompetent, which could be another possibility, then I think the incompetent physician needs to be kicked out of Medicare and Medicaid, and as far as I am concerned they should give up their license to practice medicine from now and forever more.

Equally serious is the physician who is gaming the system because they succumb to some sort of a hospital pressure. As far as I am concerned, they too should be kicked out of Medicare and Medicaid now and forever more. They have violated their basic Hippocratic oath.

So we are working to that end. One of the other things that we are doing to encourage the system is to use the PRO's, which, unlike the old PSRO Program, before PPS, have the authority to recommend sanctions. The inspector general for the Department does the actual sanctioning of health providers whether they be practitioners or they be hospitals. We take them out of the system if they are not delivering quality services that we are paying for.

We have found that it is very uneven. Some PRO's are doing a pretty good job; most are not. We feel that we must get on top of those PRO's that are really not being aggressive in looking at the quality care issue, and if they can't do the job, then get them out of the program and get somebody who will do the job.

Therefore, we are proceeding on a wide and varied front. The last point I would make is that we have been doing a separate study of whether we are paying the hospitals enough. I mean, are the hospitals in such a squeeze that they can't deliver quality health care as is provided by Medicare?

We have looked at about 50 percent of all of the participating hospitals in Medicare and have found that during the first year under PPS they were averaging about 15 percent profit on Medicare. This apparently shows that they have enough money to do the job, and there is, by no stretch of the imagination, any kind of an excuse for them to feel that Medicare is not reimbursing them sufficiently for them to provide quality health care.

So all of those reports, all of those efforts are on line and we will keep you and this committee informed as to everything that we do along the line by submitting our reports as they come off.

COOPERATION WITH PROSPECTIVE PAYMENT COMMISSION

Senator HARKIN. Are you working with the Prospective Payment Commission?

Mr. KUSSEROW. Oh, yes.

Senator HARKIN. Very closely?

Mr. KUSSEROW. Yes; we similarly are giving them access to everything that we are doing, the same way we are with the oversight committees in the Congress.

Senator HARKIN. From the indepth answer you just gave, from the length of it, I assume that you hear a lot about this problem too?

Mr. KUSSEROW. Yes; the one thing I would probably recommend for a hospital to do is to have a real live human being go to somebody on Medicare who is being discharged and just explain to them in 5 minutes what is going to happen to them.

One of the things that we found by our studies that deal with this basic Medicare, Social Security beneficiary population, is that as they get older, they get very suspicious of programs and they hunger for human contact. If somebody would come and say to Mrs. Jones, you are going to be discharged because you no longer need acute care treatment, but we are going to put you in a skilled nursing facility where

they are going to give you physical therapy. Then when they release you from there if you still need services you are going to have home help. Medicare is not going to abandon you, but is going to continue to support you. I think that would go a long way to arrest some of the concerns that currently are causing a lot of our beneficiaries problems when they go into the hospital setting.

OFFICE SPACE COSTS

Senator HARKIN. Switching to a different topic, in fiscal year 1986 you received $1.3 million to consolidate office space to reduce future rental costs. How has the plan been implemented and what is the explanation for the fiscal year 1987 rent increase?

Mr. KUSSEROW. We are making progress on that. I will tell you that the largest problem we face is the fact that we have been on notice by the General Services Administration [GSA] around the country that they are going to raise our rent charges.

As we reduce our space to reduce our costs—and our plan is bringing us way below the GSA standard—we have seen that they are escalating their rent charges faster than we can create savings. GSA advised us recently that for our New York office they are going to increase our rent, in fact double our rent over the next 2 years.

So if I have a 50-percent reduction in space, they double the rent and I am back where I started from. Much of the problem results from the fact that GSA just seems to want to escalate. I think there is a larger problem in the fact that as many agencies try to reduce space, GSA still has to pay for all of the vacated space. So they will raise the charges for everybody who remains. Thus, we are still paying the same amount. It is a catch 22 type situation. I am not very happy about what I am seeing in that arena and I think I am going to start squealing a little loudly on the subject that GSA needs to get on top of their own act.

CHARGES TO THE TRUST FUNDS

Senator HARKIN. On the trust fund, the past 3 years the trust fund portion of your budget has increased. Some 9 percent of the total in fiscal year 1985 and 57 percent in fiscal year 1987—a sixfold increase. Are you spending half your time and resources on Social Security?

Mr. KUSSEROW. No; far more than that Mr. Chairman. The fact is the 9-percent figure you are referring to is an aberration because we have functional transfers that were units supported entirely by the trust funds which were not included in that year but were rectified in the following year.

Senator HARKIN. So you are spending more than one-half of your time?

Mr. KUSSEROW. Oh, yes; the fact is we are putting more than one-half our time into that part of the Department which represents the lion's share of the outlays of our Department, Medicare, and Social Security.

The results from last year where we had significant fines, savings, restitutions, and settlements for our Department's programs, indicate that 70 percent of it was for the trust funds. We turned those funds back to the Medicare title XVIII and to the Old Age and Survivor's Insurance Program of Social Security.

So the beneficiary of our servicing Social Security in a far more heavily committed manner is paying off for those trust funds.

REORGANIZATION OF OIG

Senator HARKIN. On reorganization, last year you described your agency as having an Office of Programs Inspections and an Office of Health Care Financing Integrity. This year both are missing, and you have begun a new Office of Analysis and Inspection.

Again, for the record, what is the reason for the reorganization and how will it help you maintain a focus on health care?

Mr. KUSSEROW. Mr. Chairman, I had previously pointed out that we had functional transfers from the operating divisions of HHS. One of the functional transfers related to the staff that we got from the Health Care Financing Administration. They, in large measure, made up the Office of Health Financing Integrity, or OHFI, in our office.

What we had were two offices, our Office of Program Inspections, or OPI, and OHFI, that were engaged in inspectional activities remarkably similar. There was an overlap between the two. There was an overlap between that OHFI and the Office of Program Inspections, so to streamline the operation we consolidated all of the inspection functions in a single office and all of the investigative functions in a single office and had a 25-percent reduction in management overhead.

But once again, it is not a question of backing away from a commitment to health care. We, in fact, are still accelerating our commitment to service the health care programs of our Department.

That is evidenced in other ways, too, other than just the financial side. In 1981, our Department had 39 health providers that were sanctioned by our Department and kicked out of Medicare and Medicaid. That function was transferred to the inspector general in 1983. This last year over 390 were sanctioned. We have had a 900-percent increase in the number of people that we have kicked out of the program because they have engaged in patient or program abuse.

The same thing is true in the conviction side. So we are really accelerating our efforts in this area, not decelerating. And we will continue to accelerate, continue to put more resources in this area.

OFFICE SPACE IN FEDERAL BUILDINGS

Senator HARKIN. Thank you, Mr. Kusserow. Senator Burdick?

Senator BURDICK. Thank you. I missed the first part of your testimony. I am sorry. You were talking about rentals, future rentals, when I came in.

How many of your Department's offices are contained in Federal buildings?

Mr. KUSSEROW. I am just guessing. If you want it in more detail I will have to give it to you for the record. I would have to guess that about 85 percent are in Federal buildings.

[The information follows:]

OIG OFFICES IN FEDERAL BUILDINGS

We presently house all departmental operations in 68 buildings throughout the country. Forty-eight buildings (71 percent) come under Federal control; 20 buildings (29 percent) are owned by the private sector.

FEDERAL BUILDING RENT INCREASES

Senator BURDICK. Then rent increases wouldn't affect those.

Mr. KUSSEROW. No, Senator; in fact, that if the truth be known, in most places GSA is raising rents, and in some cases, at a very fast rate. I could probably cut my costs rather than have them increased if I could be allowed to seek private rental space.

Senator BURDICK. Just explain to me how the costs on the Federal building increase?

Mr. KUSSEROW. It is a mystery to me. I can't see how when you have a captive clientele that you can just completely raise the charges and have the building space right across the street in the exact same area that is privately owned available at a fraction of the cost it is in a Federal building.

I would suspect that there might be some need for a little more efficiency in the General Services Administration and how they operate their program. But one of the problems is that as we are trying to contract our space for Federal employees—not just for the Office of the Inspector General, but for our whole Department, for the whole Government—what we are doing is vacating space that the Federal Government still has to pay for.

So GSA is still charging the same amount no matter what happens. I can reduce my office space by 50 percent and conceivably have to pay the same amount of rent.

Senator BURDICK. Maybe we ought to have a little talk with GSA.

Mr. KUSSEROW. I think that would be a wonderful idea, Senator Burdick.

Senator HARKIN. Maybe some of our offices in the States, too, Senate offices in the States.

Senator BURDICK. Thank you, that is all.

PREPARED STATEMENT AND QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Mr. Kusserow, thank you very much. We have some questions we will submit for the record. If you would respond to those for the record.

Mr. KUSSEROW. Of course, Mr. Chairman. Thank you.

[The information follows:]

Statement of Richard P. Kusserow

Good morning, I am Richard P. Kusserow, Inspector General of the Department of Health and Human Services (HHS). I am pleased to appear before you to discuss the president"s FY 1987 budget proposal for the Office of Inspector General.

For FY 1987, our budget proposes $69,716,000 in total obligational authority of which $29,716,000 is requested in FY 1987 budget authority, and $40,000,000 is proposed for transfer from the Social Security and Medicare Trust Funds. The $69,716,000 total obligations request represents a $878,000 increase from the comparable level for FY 1986. The president"s appropriation request of $29,716,000 is within the amount authorized under P.L. 94-505. Reimbursements from the Social Security and Medicare Trust Funds are increased by $10 million to more accurately reflect Office of Inspector General (OIG) work in direct support of the programs financed by these trust funds. This shift in the source of OIG funding results in no change to the OIG'S program level. The budget authority also reflects a reduction of $1,222,000 from FY 1986 budget authority for savings from office space renovation and rental costs.

Since 1981, the Office of Inspector General has actively fulfilled its statutory mission of providing leadership and coordination and recommending policies designed to promote economy and efficiency and preventing fraud and abuse in the Department"s programs. As in the preceding years, we are continuing to keep our efforts in line by proportioning our staff resources consistent with the major allocations of the Department"s total budgetary outlays and areas of high vulnerability. Consequently, Social Security, Medicare and Medicaid, the Grants and Internal Financial Systems continue to consume the bulk of our audit, inspections and investigative resources. This redirection has, in turn, resulted in a continuous and progressive rise in our prosecutions, sanctions and savings and recoveries; all done with no real budgetary resource increase to my office over the last 5 years. FY 1985 was no exception as is indicated by the attached graphes.

During that fiscal year, we continued to practice our approach of improving OIG management by increasing our efficiency and effectiveness. Our accomplishments, as illustrated in our Semiannual Report, continue to exceed our earlier expectations. During FY 1985, over $4.9 billion in settlements, fines, restitutions, recoveries and savings were idenified, thus supporting our upward trend. This represents a 3000 percent increase since 1981 and a return ratio of nearly $68 for each dollar spent to support OIG activities for FY 1985.

During the same timeframe our investigative efforts rose from 165 to over 1,005 successful prosecutions in FY 1985, a 600 percent increase. Also, we obtained administrative sanctions against 390 health providers and suppliers "kicked out" of the Medicare and Medicaid programs for program and patient abuse (a 19 percent improvement from FY 1984 to FY 1985 and a 1000 percent increase in the last 5 years). Both our level of prosecutions and level of sanctions represent progress over last year's achievements, and again, I point out that these results were achieved by better

targeting the use of OIG resources for improved efficiency and effectiveness.

For FY 1987, the majority of our work will come from program operations, comprised of the Offices of Audit, Investigations, and Inspections and Analysis. The bulk of the OIG staff is divided among these components, with the Office of Audit having the largest staff complement. As mentioned previously, the workload of these components is devoted mainly to the big expenditure programs of the Department ... Social Security, Medicare, Medicaid, and Public Health ... programs which consume more than 95 percent of the Department's total resources.

The Medicare and Medicaid programs, administered by the Health Care Financing Administration (HCFA), provide health care for approximately 50 million Americans; nearly one out of every five citizens. For FY 1985, OIG recommendations adopted by HCFA and legislation resulting from OIG findings resulted in $3.0 billion in savings in Medicare and Medicaid. Further recommendations are under consideration. For example, we pointed out that some capital and medical education costs are improperly included in the cost base for the current diagnostic related group rates. Excluding those charges could prevent annual overcharges to the Medicare program of $770 million. An OIG inspection of three DRGs identified substantial vulnerabilities in coding. The findings identified overpayments in excess of $20 MILLION.

In FY 1987, significant resources will be devoted to Medicare/ Medicaid programs in order to identify ways to contain health costs - particularly in the area of reimbursement for hospital and physician services. For example, OIG will continue to assess implementation of the Medicare prospective payment system (PPS). In addition, we plan to expand our evaluations of PPS abuses, such as improper coding of medical records, underutilization of services, unnecessary admissions, readmissions and inappropriate transfers or discharges.

Due to the large outlays of the Social Security Administration's program and the costly operational problems that persist, the Office of Inspection General will continue to commit a significant portion of its resources to SSA programs. OIG reviews focused on conserving trust fund resources, insuring the accuracy of SSA payments and increase debt collection. SSA continues to respond favorably to OIG reports. For FY 1985, SSA concurred with OIG recommendations which identified additional savings of $321.1 million. For the coming year, we will continue to work to improve management and fiscal controls over benefit payments, administrative costs, asset management of the trust funds. In addition, we plan to increase our use of computer assisted techniques in our investigative and audit work to enhance and improve the efficieucies of our human resources. The increased use of computer techniques has resulted in the identification of thousand of cases where individuals fraudulently received or were erroneously paid millions of dollars that they should have never received. Improvements in computer fraud detection techniques are making it possible to take one known case and screen for others.

For those programs falling under other departmental components, such as Public Health or Human Development Services, we will

continue to make a high priority the identification of cost savings through consolidation of overlapping activities, productivity improvements, tighter controls over cash disbursements and collections, and other changes in processes and systems designed to improve management efficiency and ensure financial integrity. Our Grants and Internal systems will, therefore, increase the assessments of internal controls while performing management and efficiency audits of departmental operations. We will also increase the continuing oversight and technical analysis of all nonfederal audit reports received of single audits on an entity-wide basis.

Finally, we will continue to review departmental regulations and legislative proposals for vulnerability to fraud and abuse and develop new cost effective proposals for legislation. During FY 1985, we received over 500 HHS regulatory and legislative change proposals. We expect this process to result in many significant program safeguards during the next fiscal year.

In closing, Mr. Chairman, let me assure you that this office is making every effort to provide a comprehensive and systematic program for rooting out fraud, waste and abuse in the Department's programs. The entire OIG staff is very dedicated to finding ways to save money in the Department's programs. But more important, we are dedicated to making sure that the resources set aside in our programs are delivered to the beneficiaries they are intended for. We strongly believe that the indirect impact of our work far exceeds the dollars we are returning to the American taxpayer. I will be pleased to answer any questions you may have.

Questions Submitted by the Subcommittee

FULL TIME EQUIVALENT CUTS

Question. Your FY 1987 budget request proposes 1,214 full time equivalents (FTE) -- a reduction of 100 below the FY 1985 level. Yet you still plan a $5 billion in saving recommendations -- almost the same dollar amount as in FY 1985.

a. How do you sustain savings outputs when you loss 100 auditors and investigators?

b. May we hear some specific examples of how you do this?

Answer. Savings output, given a staff reduction of 100 auditors and investigators can be sustained in the long run only by increases in efficiency. In the short run, however, savings outputs might be sustained due to the normal lag time between the time we complete an audit, investigation or inspection and the time at which a sanction, saving or conviction occurs and is reportable. An example of this is in the unimplementable recommendations that exist in our semiannual report which are subsequently resolved. If, for any one of a number of reasons, management does not agree to implement our recommendations, no savings would be reported. In FY 1986, however, if management agreed or Congress passed legislation to implement our recommendations, a savings would be reportable. So at any given time, there is an inventory of

unimplemented OIG recommendations which could become savings if management or Congress acts.

In my Semiannual Report to Congress for the period of April 1, 1985 to September 30, 1985, a cost savings of $26.3 million was reported after the Health Care Financing Administration (HCFA) in FY 85 revised the Provider Reimbursement manual to prohibit providers from retroactively adjusting equity capital when computing Medicare's share of the gain on sale of assets. The audit report which is the basis for this savings, was issued in FY 84.

Also included in the same semiannual report was an unimplemented recommendation to extend the time limit for correcting and collecting SSI payments from 2 to 4 years. If this recommendation which is still under consideration by SSA, is implemented in FY 86, a $50 million a year cost savings would be reportable.

EDP AUDIT

Question. You mentioned last year that you had set up an EDP audit division to help prevent computer fraud and abuse. Give us some examples of what has been accomplished.

Answer. The OIG is reviewing, on a continuing basis, selected SSA system development projects included in its Systems Modernization Plan (SMP).

We view SSA's software overhaul as a most critical long range system problem. Our systems reviews focus on software improvements with the objective of ensuring that future software will have adequate internal controls and be maintainable, and thus flexible to SSA's changing needs. Our ongoing reviews to date have focused on two critical activities.

First, the SMP called for improvement of software prior to its incorporation into new modernized systems. This effort was delayed, and as a result it is now questionable whether the improvements called for will be completed in time for the new systems being developed. We have reported on problems and delays in improving software and recommended corrective action.

For example, one of our first reviews dealt with SSA's award of three computer software contracts to assist in its systems modernization effort. Our review disclosed that despite expenditures of over $1 million and 10 work years of scarce in-house systems personnel time (or about $407,000 in salary costs) in attempts to improve delivered products, only minimal improvements resulted. Much of the software delivered by contractors was either of no use to SSA or usable only after considerable modifications.

We found that the underlying causes for the generally poor results were that: (1) software improvement, in itself, is extremely difficult to accomplish and is made even more so when done under contract; (2) SSA has little experience in planning, writing, and monitoring software improvement contracts; and (3) there was a sense of urgency by SSA to make quick software improvements which resulted in unrealistically short deadlines for completing work.

We recommended that SSA implement the necessary procedures and controls to ensure that useful products result from contracts for software improvements. SSA agreed to implement all of our recommendations.

Although SSA has taken some steps to strengthen their software program, we still have concerns. We believe that past problems could easily recur such as changes in priorities and management or that increased staffing pressures in technical areas will cause further delays. We believe that these delays can be avoided only by a continuous, high-level commitment by top management.

Secondly, we are reviewing the development of SSA's new Title II claims processing system. This system is one of the two largest, most complex of SSA's systems and is critical to the overall success of the SMP. The first phase of development is the automation of the initial claims input process. SSA plans to put in place by 1987 a 20,000 terminal network which will allow automated claims-taking in 1,500 offices with concurrent access to major SSA data files. OIG has recently completed a review of SSA's prototype of this system and will be issuing a report shortly focusing on system maintainability, internal controls, and documentation.

- We also expanded coverage into Medicare/Medicaid Public Health Service and Office of Human Development Services areas. OIG reviews of physical security at NIH and OHDS EDP facilities and at 16 Medicare contractors disclosed weaknesses. Specifically, weaknesses were found regarding physical access to computer facilities, disaster recovery and contingency planning and the use and protection of passwords for accessing computers. These weaknesses increase the vulnerability of the computer systems to fraud, embezzlement, unauthorized disclosures, destruction and misuse. Recommendations call for actions to strengthen security which will eliminate the weaknesses noted and lessen the vulnerability of these facilities and their systems to the recurrence of these weaknesses.

  We are now looking at controls over access to sensitive Food and Drug data and the internal controls at a State Medicaid Facility. In general, we are finding that security is still a problem in HHS controlled facilities.

- We have also looked at the departmental administration area. Since 1973, operating/staff divisions of the Department have used a relatively expensive commercial on-line time-sharing service to assist in preparation of the annual budget and five other administrative reports. Our review of the contract and the application systems found that the time-sharing arrangement is costly because the contractor's services are relatively high priced and budget development is labor intensive. For example, the charges to connect into the contractor's systems are five times greater than the charges to connect into an in-house computer. There are, we found, feasible alternatives to the present time-sharing systems which could save HHS about $2.6 million over 5 years and, at the same time, improve operations and reduce staff time needed to input data and create reports. We recommended that the time-sharing service contract be ter-

minated and the work be performed using generalized software on in-house micro-computers with linkage to an in-house mainframe computer when necessary. HHS agrees and is shifting their workload from time-sharing to in-house computers.

- Finally, we are providing assistance to the Department in implementing its new accounting system. Our involvement has primarily been in the area of internal controls. We re working to ensure that controls are built into the system rather than tacked on later. We are developing a "model" which defines the "who, how and when" for implementing controls in a new system. This model will be applied to the accounting system while it is being designed and developed. When implemented, the system will have controls built in which are documented and show how the system complies with all statutory, GAO, OMB, GSA and departmental systems control requirements. Also, the model will be generic so it can be applied to almost any system under development.

SAVINGS PROJECTIONS

Question. a. How do you estimate the saving projections on Page 91 of your justification?
b. Is the 4.9 figure a compilation of many smaller audits?
c. Are the savings for one audit finding repeated in more than one year?

Answer. At any given time there is an inventory of unimplemented OIG recommendations. We also have other work in process which will result in recommended savings. The $4.9 billion dollar figure is our best estimate of cost savings which will result in FY 87 as a result of management or Congressional action on these recommendations. It is not based on national extrapolations of many small audits. Rather, most of the computations are based on recommendations which affect the cost of programs nationwide. If savings are the result of Congressional action, we report to CBO their phase-in estimate over the budget cycle. Savings are not repeated in more than one year.

NATION'S UNIVERSITIES

Question. The nation's universities play a vital role in advancing U.S. health by performing over half of the basic health research and educating of future researchers. Can you explain what the Office of Inspector General has done to oversee the expenditure of funds in colleges and universities?

Answer. The Public Health Service (PHS) awards over $4 billion annually to colleges and universities. We have oversight responsibilities for audit cognizance at some 95 percent of the nation's colleges and universities. Because we rely on the work of independent auditors to provide basic audit coverage at the majority of the colleges and universities, the primary thrust of our efforts are now directed toward audit coverage of the large dollars in research and development and student financial aid.

NON-FEDERAL AUDITORS

Question. With the emphasis toward the Inspector General's relying more and more on work done at the recipient or grantee level by non-federal auditors, what steps are you taking to assure that the Federal Government is receiving quality audit products?

Answer. The contribution of the single audit to our work continues to grow quantitatively and qualitatively. During the last 16 months, we received, evaluated and issued 805 reports containing recommendations for cost recoveries of $10.9 million and over 1,600 identified opportunities for improving the efficiency of grantee management systems. To a large measure, these results are attributable to the increasing emphasis the OIG has placed on integrating single audits into its operations.

To provide uniformity nationwide, we have issued uniform operating procedures for working with CPA firms, state auditors, recipient organizations and other Federal agencies. The procedures provide guidance in areas such as processing single audit reports and performing quality control reviews, along with direction for the disposition of substandard audit reports. We have also made extensive progress in putting into operation our newly developed automated system to monitor the quality of audits, track their progress and record all FY 86 non-federal audit activity impacting on HHS programs. This system will provide the information necessary for reporting to Congress in our semiannual report on non-Federal audit activity.

INDIRECT COST

Question. Your office recently issued a study report on the subject of indirect cost charged to Federal research grants and made several recommendations which substantially impact the indirect cost process. What is the current status of this issue?

Answer. Our main recommendation was that OMB Circular A-21 be revised to provide for a fixed allowance of 7 percent for departmental administration.

Our study report is only one of many pieces of information used by the Department of formulate the current proposal to establish a fixed allowance for the administrative components of university indirect costs rates. This proposal is based on studies by GAO, the White House Office of Science and Technology Policy (OSTP) and the HHS OIG which concluded that most of the administrative cost included in university indirect cost rates are virtually impossible to measure or evaluate in terms of the relevance to sponsored research programs. All three groups recommended that the Government move to the use of a fixed allowance for administrative components.

On February 12, OMB published a notice in the Federal Register inviting comments on the proposed revision to OMB Circular A-21, "Cost Accounting Principles for Education Institutions."

The provisions which we basically support require the establishment of a 26 percent limit on overhead allocated by universities to Federal research grants effective April 1, 1986 and a 20 percent

fixed rate effective April 1, 1987. This approach makes eminent good sense.

After the issuance of our study report we have been contacted by an educational interest group and one university expressing concern with our conclusions. We have been in contact with the concerned parties and are available to meet with anyone that has any specific information relative to our study.

The university that contacted us advised that the situation presented in our study report does not exist at their institution.

Because our conclusions were drawn from 13 schools, summarized in our report, and statistically projected to show impact on the total educational environment it is not possible to relate the summary data to specific instances at an individual school. However, we are in contact with the institution officials to discuss their concerns.

INDIRECT COSTS STUDY

Question. Can you expand upon the information presented in your report as well as how you arrived at your conclusion?

Answer. The growth of indirect costs, as a share of total research grant costs, has been the subject of numerous studies over the last 10 years by universities, congressional committees, private organizations and Government agencies. With regard to the growth of indirect costs, we estimate that from 1978 through 1984, annual pay-ments to universities and colleges for indirect costs increased from about $900 million - an amount equal to 36 percent of the funds used for direct research in 1978 - to $1.7 billion which is equivalent to 46 percent of the $3.7 billion provided for direct research in 1984.

Our study approach was to review objectively indirect cost trends over a period of time rather than basing our study on a snapshot. As part of our study, we developed a computer model to establish an average departmental administration rate that, in our opinion, will provide universities with a reasonable allowance for research administration at the department level.

We used data covering a 6-year period, compiled from 13 of the top 100 research universities, as the primary basis for our study. Although approximately 650 of the nation's 2,700 universities and colleges receive research funds from the Federal Government, the top 100 receive about 85 percent of the total amount awarded.

The universities we studied are:

Harvard (PR)	Johns Hopkins (PR)
U. Iowa (P)	UC - Los Angeles (P)
Yale (PR)	U. Pennsylvania (PR)
Washington U. (PR)	UC - Berkeley (P)
Boston U. (PR)	Temple (P)
U. Missouri (P)	U. Massachusetts (P)
U. Connecticut (P)	

(PR) - Private School

(P) - Schools wholly or primarily supported by State appropriations.

The univesities received an estimated $760 million in fiscal year 1984, or about 17 percent of the research funds made available by the Government to the top 100 schools. The ratio of indirect costs to direct research costs for the universities studies was about 51 percent in fiscal year 1984 as compared to 46 percent for all research universities and colleges. Under these circumstances, we believe the 13 schools included in our study are representative of the top 100 universities receiving research funds from the Federal Government.

During our study, we held discussions with and/or obtained data from representatives of the Office of Science and Technology Policy, National Science Foundation, Office of Naval Research, the Council on Government Relations, and HHS's Public Health Service, National Institutes of Health and Office of the Assistant Secretary for Management and Budget.

Generally, we found that most increases in indirect costs are reasonable and beneficial to research sponsored by the Federal Government, except for those increases applicable to the pool of indirect costs referred to as "departmental administration." For the most part, increases in the other indirect costs pools were caused by inflation; special and scientific studies conducted by universities to related buildings and equipment usage and related energy and fuel costs to Government sponsored research; and increased conversions from use of allowances to depreciation. With respect to the departmental administration cost pool, where payments increased from an estimated $275 million in fiscal year 1978 to an estimated $575 million in fiscal year 1984 - or to an amount equivalent to 15.4 percent of the direct cost of scientific research, we estimate that in fiscal year 1984 over $300 million of such payments did not benefit and, therefore, should have been allocated to the major university functions of instruction and other institutional activities. Departmental administration costs that we believe were not beneficial to Government sponsored research, although difficult to identify, quantify and challenge under the current provisions of Office of Management and Budget (OMB) Circular A-21, include (1) faculty salaries, (2) certain clerical and technical salaries and other operating expenses, and (3) certain costs allocated to departmental administration from other indirect costs pools.

Accordingly, our study confirmed the existence of savings opportunities and led us to recommend a fixed allowance for the highly

controversial departmental administration component of the indirect cost rate.

HEAL PROGRAM

Question. In March 1985, the OIG issued its report on a study of selected lenders and schools participating in the HEAL program. Among other findings, the review determined that the HEAL program was threatened by insufficient insurance premiums, unnecessary borrowing, and ineffective collection requirements that endangered the solvency of the fund used to pay default claims of HEAL lenders. What actions have been taken to help ensure solvency of the fund?

Answer. In response, Congress and the Department implemented several actions to help ensure the solvency of the fund. Legislation enacted October 22, 1985, the Health Professions Educational Assistance Act of 1985, P.L. 99-129, addressed OIG recommendations such as:

- Increased the maximum HEAL insurance premium rate from 2 percent to 8 percent.

- Authorized the Secretary to increase the premium to 8 percent upon determination by a qualified CPA firm that additional funds are needed to keep the fund solvent. The CPA actuarial study and report is due May 30, 1986. We anticipate that the maximum rate of 8 percent would be effective July 23, 1986.

- Permitted HEAL borrowers the option to select a repayment schedule incorporating negative amortization during low earning years.

- Limited deferments for repayment to 4 years for residency and internship, to 3 years for service in the uniformed services or Peace Corps, and to 2 years for full-time health education. The loan repayment period can not exceed 33 years from the date of execution of the loan agreement to final payment.

Regulatory actions were taken to improve communications among lenders, schools and borrowers, and to make due diligent requirements more comparable to commercial practices. Proposed HEAL rulemaking, now being reviewed by the Secretary, includes recommended actions to tighten controls over unnecessary borrowing and strengthen the collection process of lenders.

HEAL STUDY

Question. Have you performed any further audit work in the HEAL program since the issuance of your 1985 HEAL study on HEAL lenders and schools?

Answer. Our office, in cooperation with Public Health Service, is conducting a follow-up review of the management of the HEAL program. The review is a continuation of the ongoing OIG efforts for improving loan and debt collection. Our primary focus is on loan monitoring and data collection procedures, and includes an assessment of current management actions to avoid a further escalation of the rising HEAL default rate. The Office of

Management and Budget has asked that we address certain specific interests including the allocation and redistribution of loan authority.

HEAL LOANS

Question. How much is currently guaranteed under HEAL loans?

Answer. At September 30, 1985, HEAL had guaranteed over $845 million in loan principal made by 67 lenders to over 54,000 students. Accrued interest would increase total loan guarantees to over $949 million. Of the $845 million loaned, $146.7 million was in repayment status. Of that amount, about 13 percent or $19.4 million was more than 60 days past due.

OIG REVIEW OF HEAL PROGRAM

Question. What has the current OIG review of the HEAL program disclosed?

Answer. The audit is still underway, but preliminary data has shown that the operational data necessary to effectively administer the program needs to be improved. The upward trend in HEAL loan defaults during FY 1985 and the current fiscal year is continuing. Default claims totaled $5.9 million in the first quarter of FY 1986 and were growing at a rate that again could endanger the solvency of the fund. We attribute this condition to delays in implementing actions to strengthen due diligence regulations and to link insurance premium rates to default rates in high risk disciplines. These were recommendations we made earlier.

As of September 30, 1985, the HEAL program has paid lender claims of $13.6 million on 777 claims since inception, for an overall claims rate of 8.5 percent. Claims include defaults, bankruptcies, death and disabilities. By comparison, at September 30, 1984 the HEAL program paid cumulative lender claims of $5.5 million on 361 claims, for a claims rate of 5.7 percent.

HEAL claims paid during the first 4 months of FY 1986 amounted to $6.7 million for 328 claims. This denotes a 256 percent increase over the $2.6 million for 131 claims paid during the same period in FY 1985. Analysis of HEAL borrowers by profession shows that claims paid for the disciplines of dentistry, podiatry and chiropractic for the 4-months ended January 31, 1986 amounted to $4.8 million for 207 claims, representing 72 percent of defaulted claims.

HPSL/NSL

Question. You issued a report on cash management problems associated with HPSL/NSL schools in 1982. Have you done any follow-up reviews on this area?

Answer. Yes, we recently found cash management problems at several institutions participating in the HPSL/NSL programs. Each participating school establishes a revolving fund to finance student loans. (It's constituted from a 90/10 sharing of Federal and State contributions.) Our computer assisted analysis of the

HPSL/NSL funds at 17 schools identified $1.5 million institutions had not deposited the earnings into the loan fund as required.

We also have preliminary data that certain schools may be maintaining fund balances that are in excess of loan demand and delaying the write-off of loans that have been delinquent for long periods. Often delays by schools in obtaining write-off authority from the Department suggest that schools may not have exercised proper due diligence in recovering delinquent debts. If due diligence was not practiced, schools must reimburse the fund 100 percent of the delinquent amount.

BUDGET

Question. Your FY 1986 budget shows a $4.3 million reduction due to the sequester order. If a similar or larger amount was requested for FY 1987, what would the affect be upon the progress you have to date in savings, fines and restitutions to the Government?

Answer. At present, savings are being accomplished through staff reductions which have been handled through normal staff attrition. In addition, for FY 86, we are also absorbing costs through extensive space reductions, limiting our travel allowance, reductions in such areas as non-recurring contracts, equipment repairs, work orders and rental payment to GSA. Consequently, we expect no change from our programmed level of activities and savings.

For FY 1987, if there is no change to the OIG budget, we foresee little impact upon our operation. However, with additional reductions in resources and staff allocations, we can expect significant reductions in savings and recoveries from our present level.

FRAUD AND ABUSE

Question. How much fraud do you believe currently exists in the Medicare, Medicaid and Social Security programs?

Answer. It is very difficult to project a sound estimate. What we do know is that we seem to be better able to get at major problem areas; identify the extent of the problem and permit management to take corrective action. In part that represents whey we are having such a large increase in our statistical results. I do not necessarily believe that it is the result of having more waste, abuse, fraud or mismanagement, but rather that we seem better able to identify with it.

Question. What have been your offices' major initiatives this past year? How much money have these projects saved the Government?

Answer. As reported in our latest semiannual report (April 1, 1985 - September 30, 1985), major OIG accomplishments included:

- Administrative sanctions imposed by the OIG resulted in 280 health care providers being "kicked out" of the Medicare and/or Medicaid programs for health care related fraud and for providing for poor quality of services bringing it to a record total of 390 for the year.

- Accepted OIG recommendations for legislative, regulatory, or operating policy changes, and HHS management commitments to recoup overpayments which have an aggregate dollar value of nearly $2 billion for the six month period and a total of $4.9 billion for the fiscal year.

- Investigation of Social Security fraud resulted in 386 successful prosecutions and $25 million in recoveries and savings, for a record year total of 854 successful prosecutions and $35.5 million in recoveries and savings.

- Investigations of Medicare/Medicaid fraud by the oIG and federally-supported State Medicaid Fraud Control Units resulted in 245 convictions, and financial recoveries and savings of $11.1 million. This included $6.7 million in civil monetary penalty settlements. Total fiscal year results were 480 Medicare/Medicaid convictions and financial recoveries, settlements and savings of $20.9 million.

INTERMEDIATE CARE FACILITIES FOR THE MENTALLY RETARDED (ICF/MR)

Question. During our hearings last year the suggestion was made that after treatment services for residents of intermediate care facilities for the mentally retarded should be more clearly defined in the Medicaid program. Has the Department submitted a legislation proposal to clarify the definition of After Treatment services or have clarifying regulations been published?

Answer. In respone to the OIG's concern regarding clarification of HCFA's ICR/MR educational cost policy, HCFA agreed to work with a state technical advisory group to develop an ICR/MR educational cost policy clarification. This clarification was issued in September 1985 through the State Medicaid Manual.

Questions Submitted by Senator William Proxmire

CAPITAL AND MEDICAL EDUCATION COSTS

Question. Your prepared statement refers to the fact that you pointed out some capital and medical education costs are improperly included in the cost base for the current diagnostic related group rates under the Medicare program. You indicated that excluding these charges could prevent annual overcharges to the program of $770 million. Can you tell us what steps have been taken to correct the situation since you made your findings?

Answer. To correct for the improper inclusion of capital and medical education costs in 1981 hospital cost data used in setting DRG rates, we recommended that HCFA rebase the Federal portion of the prospective payment rates using a more current year's audited hospital costs. Rebasing would recompute the standardized amount of average hospital cost using correct data. HCFA has not acted on our recommendation. HCFA has stated that since the regulation on the FY86 rates held rates to to the FY 85 level, an adjustment for these factors would have had no practical effect. We are continuing to work with HCFA to implement our recommendation.

PROSPECTIVE PAYMENT SYSTEM

Question. In your prepared statement you refer to "underutilization of services" as an abuse under the prospective payment system. Could you elaborate on that remark?

Answer. Under the Prospective Payments System (PPS) hospitals have an incentive to increase the efficiency and effectiveness of their services. When new efficiencies translate into an underutilization of services to patients, there is a potential for abuse of the system. We are working closely with HCFA to ensure that an adequate peer review system is in place to monitor the utilization of services.

INDIRECT COSTS

Question. On page 94 of your justifications you mention OIG identified opportunities to contain indirect costs of federally sponsored research resulting in savings of $315 million annually.

Summarize those recommendations for us and tell us whether or not they are being implemented by the Department.

Answer. Our main recommendation was that OMB Circular A-21 be revised to provide for a fixed allowance of 7 percent for departmental administration. We identified an opportunity to contain these costs and make $255 million available annually, or about $1.3 billion over a 5-year period, to meet other budgetary need of the Government, including the financing of thousands of unfunded research projects already approved for technical merit.

Our study report is only one of many pieces of information used by the Department to formulate the current proposal to establish a fixed allowance for the administrative components of university indirect cost rates. This proposal is based on studies by GAO, the White House Office of Science and Technology Policy and the HHS OIG which concluded that most of the administrative cost included in university indirect cost rates are virtually impossible to measure or evaluate in terms of their relevance to sponsored research programs. All three groups recommended that the Government move to the use of a fixed allowance for administrative components.

On February 12, OMB published a notice in the Federal Register inviting comments on the proposed revision to OMB Circular A-21, "Cost Accounting Principles for Education Institutions." The comments received are being analyzed by OMB, who will issue the governmentwide policy.

The provisions which we basically support require the establishment of a 26 percent limit on overhead allocated by universities to Federal research grants effective April 1, 1987. This approach makes eminent good sense.

SOCIAL SECURITY ADMINISTRATION

Question. In a response submitted for the hearing record last year, you indicated your FY 85/86 work plan allocated substantial resources to a study of the Social Security Administration's work measurement system. Please give us a progress report.

Answer. This particular study was rescheduled and included in our FY 87 work plans for two reasons. First, GAO is doing a top to bottom review of management operations at SSA including many selective aspects of SSA's work measurement system. Their report is targeted for release in September. We will evaluate what GAO has done in this area and will assess what additional work measurement studies need to be done by my office. Secondly, other areas to shore-up the trust funds were in process and required additional resources for their completion. For example, assessment of overpaid FICA taxes paid to taxpayers by IRS through tax return adjustments on behalf of SSA and the reviews for controlling overpayments and incorrect payments. These two items will be reported in my next semiannual report.

FEDERAL MANAGERS' FINANCIAL INTEGRITY ACT

Question. Can you briefly summarize the progress being made by the Department in meeting its responsibilities under the Federal Managers' Financial Integrity Act?

Answer. we have spent considerable time working with the Department to fulfill the requirements of the Federal Managers' Financial Integrity Act (FMFIA) (P.L. 97-255) which requires Federal agencies to establish a continuous process for evaluation and improvement of internal administrative and accounting control systems and publicly account for the status of their systems. A permanent steering committee, having representatives from each major Department component, including the OIG, assists in developing policies and procedures and managing the program. Additionally, we provide:

-- Assistance in the planning process
-- Technical advice
-- Coordinated efforts with the Department, GAO, and OMB
-- Critical reviews of Department efforts
-- Internal audits testing controls of operations reviewed
-- Report to the Internal Control manager and the Secretary on the adequacy of FMFIA implementation
-- Review and comment on the Secretary's annual reports to the President and the Congress

During 1985, the Department focused on (1) redefining the segmentation of programs and functions into more discrete assessable units, (2) training staff for carrying out responsibilities of FMFIA and (3) performing vulnerability assessments to weight the risk of mismanagement -- waste, loss, unauthorized use of resources; errors in reports and information; illegal acts or misappropriations. This process identifies and prioritizes areas of vulnerability for mismanagement and the need for detailed internal control reviews into such areas as cash management, procurement, grants administration, records systems property management and the budget process.

OIG, in monitoring progress under the FMFIA, reviewed the Departments third-year efforts and in December 1985 reported to the Secretary on the results of the review.

The Department had made progress in more clearly distinguishing areas for internal reviews, upgrading guides for conducting the

reviews, and training staff involved in the reviews. Milestones set for completing the internal reviews, however, were not always met. In some instances, documentation of internal reviews and reporting on the results of reviews needed improvement.

We will continue to work closely with the Department to help them upgrade their efforts in carrying out the law. Also we have been and will continue to be active in assisting the Office of Management and Budget through working with the PCMI and PCIE in developing refined implementing requirements and guidance giving full consideration to Congressional initiatives to minimize paperwork and staffing requirements.

EXECUTIVE SERVICE POSITIONS

Question. I notice that you plan to add two executive service level 5 positions to your staff in 1986 although last year's justifications made no mention of these positons. Can you tell us why you created those slots?

Answer. We did not create new slots. These level changes represent promotions for two executive service level personnel.

OFFICE FOR CIVIL RIGHTS

STATEMENT OF BETTY LOU DOTSON, DIRECTOR

ACCOMPANIED BY BART J. CRIVELLA, DEPUTY DIRECTOR FOR MANAGEMENT AND POLICY

INTRODUCTION OF ASSOCIATE

Senator HARKIN. Welcome back to the committee, Ms. Dotson. Please identify those with you for the record.

Ms. DOTSON. OK. Mr. Chairman, this morning I have with me Mr. Bart Crivella, who is the Deputy Director for Management and Policy of the Office for Civil Rights.

We are appreciative of the opportunity to present our request to you this year. We are requesting $19,285,000 in obligational authority; $15,285,000 comes from budget authority and $4 million from the Social Security and health care financing trust funds.

This request provides for 371 FTE staff, compared to 383 FTE in fiscal year 1986. This smaller staff size is consistent with the administration's program to restrain spending and reduce the deficit.

Throughout the year we intend to achieve our savings by means of attrition, controlled hiring, management efficiency, and space consolidation, consistent, of course, with what Mr. Kusserow just got through saying.

We feel that management efficiencies will result in productivity increases and will offset the FTE decreases.

In fiscal year 1987 we will carry out our proactive compliance program, which is, we feel, effective, innovative, and comprehensive in its approach to the fulfillment of our basic mission.

These efforts include voluntary compliance and outreach activities and compliance in pregrant reviews, in addition to our complaint processing. Our complaint processing will continue with a projected receipt of 1,170 new complaints.

In conclusion, we feel that our budget request will allow us to effectively carry out our mission. I would be happy to answer any questions.

SECTION 504 REGULATION

Senator HARKIN. Ms. Dotson, thank you. You indicate in your budget justification you plan to develop a regulation applying section 504 compliance standards to Department programs. Section 504 has been the law of the land for 13 years.

Why has it taken so long to bring the requirements of section 504 to the Department's programs?

Ms. DOTSON. Well, I can only respond to it since I have been here. This regulation which you are speaking of is related to federally operated programs. This regulation has been developed by our office and has been circulated throughout the Department under the regulatory clearance process.

Senator HARKIN. How soon do you expect them to be covered?

Ms. DOTSON. I don't know, because I can't control the approval process of regulations once they get outside of HHS.

GROVE CITY COLLEGE DECISION

Senator HARKIN. The Supreme Court's decision in *Grove City College* v. *Bell* ruled that the nondiscrimination requirements attached to the receipt of Federal financial assistance extend only to the particular program or activity funded and not the recipient institution in its entirety. We all know what the *Grove City* decision was.

To what extent have you been prevented from investigating alleged discrimination in recipient institutions as a result of that decision?

Ms. DOTSON. We have had no disruption of our activities due to the *Grove City* decision.

Senator HARKIN. None?

Ms. DOTSON. That is right.

Senator HARKIN. Then it wouldn't help you if *Grove City* was overturned?

Ms. DOTSON. I think it would make our job perhaps more simplistic, but the existence of *Grove City* hasn't caused us to have to turn down jurisdiction or anything like that in particular.

Senator HARKIN. How would it make your job more simplistic if *Grove City* were overturned?

Ms. DOTSON. Because, and I would make this a very simplistic answer from my standpoint, because I rely upon general counsel to interpret these things fully for us. As I understand it when we look at our jurisdictional basis when we receive a complaint, we ask a few more questions about the program or activity in the initial stages of the processing.

What I am told is that a clarification of *Grove City* would perhaps eliminate that step.

LEGAL SERVICES STAFF

Senator HARKIN. The budget request reduces your Department of Legal Staffing again in fiscal year 1987. As I have read the record, legal services staff has been reduced every year under this administration and has almost been cut in half since 1983.

In fact, legal services full-time equivalents, according to my records here, in 1983 there were 50, and that will go down in 1987 to 27. That is quite a cut.

Does this in any way mean that you are not bringing enforcement actions to the courts?

Ms. DOTSON. No; I don't feel that it does at all. I think an examination of where those cuts occurred in our legal services component will indicate that most of them occurred in our regional operations.

What we began to find when we came on board was that many of our legal counsel were, in the field especially, doing investigators' work, which is basically the job of the Office for Civil Rights' employees in contrast to general counsel.

Second, the staff level that we had in general counsel was a carry over from the days of OCR-HEW, and we just have not had the volume of complaints that we had in previous years.

ENFORCEMENT CASES

Senator HARKIN. Just tell me this. Do you have, for the record you and Mr. Crivella, how many cases have you enforced through litigation in the past 2 years?

Ms. DOTSON. I will be happy to supply that for the record.

Senator HARKIN. Also would you compare that to the record of the previous administration?

Ms. DOTSON. Yes.

[The information follows:]

ENFORCEMENT ACTIONS IN PAST 2 YEARS

Civil rights regulations provide that OCR can initiate administrative proceedings or refer cases to the Department of Justice. During the past 2 years, a total of 10 cases were in administrative proceedings or had been referred to justice (6 in administrative proceedings and 4 in judicial enforcement). Three of these cases were initiated during the past 2 years (two administrative proceedings and one judicial enforcement action). Another three judicial enforcement actions were brought prior to 1984 by this administration.

COMPARISON TO PREVIOUS ADMINISTRATION

As of December of 1980, OCR was involved in four judicial enforcement actions, the same number of such actions as in fiscal years 1984 and 1985. Additionally, OCR records indicate involvement in nine health and human services administrative proceedings during 1979 and 1980. Only four of these proceedings were initiated during the term of the previous administration—an average of one per year. During fiscal years 1984 and 1985, OCR initiated two administrative proceedings, maintaining the same annual average.

DISCRIMINATION COMPLAINTS

Senator HARKIN. The table on page 71 of your justification indicates a rise in the number of civil rights complaints in fiscal year 1987. Why do you expect the complaints to increase?

Ms. DOTSON. It is always hazardous to speculate about why our complaints increase and decrease. One cause I suspect would be our rather energetic effort to reach out to our constituencies, all of our constituencies, to inform them of their rights. Also, it may be a result of our working very closely with recipient and beneficiary organizations to tell them what recipients have to do in order to be in compliance. We have adopted a posture of not just sitting and waiting for complaints to come to us.

So we felt that maybe we needed to do a little bit more in terms of reaching out to the various constituencies.

OUTREACH PROGRAM

Senator HARKIN. How are you doing this? How are you reaching out to these constituencies to inform them of their rights?

Ms. DOTSON. First of all, organizationally we are set up so that we have a Voluntary Compliance Division which is replicated in our regional offices. Now, as part of their activities they are mandated to have an ongoing dialog with constituency groups. By constituency groups I mean advocacy groups for whatever that particular constituency is.

Second, these people also are obligated to go out to recipient agencies, State agencies, or whichever organizational unit is receiving the HHS funds to inform them and work with them to make sure they are in compliance.

Also, the process of doing a compliance review, which is a little bit short of an investigation, is something which we initiate. We pick a facility or several facilities and just go through their organization to determine what the compliance posture is. This way, we reach out.

Through this process and in whatever way we can we are telling people constantly that we are here, that we want to hear what they are thinking about. Theoretically, we don't go out and say, hey you, file a complaint. But I guess it is like "Syms," the educated consumer is the best citizen. So we are taking that approach.

CONSTITUENT GROUPS

Senator HARKIN. So you really do actively promote activist groups that are out there to come in.

Ms. DOTSON. Yes; I go out and talk to them on occasions. It is done at the regional office level. They are constantly encouraged to know these people, No. 1. Say, if it was a handicapped group, a Hispanic group, or whatever kind of group that has an interest in our programs, I expect regional offices to know who they are, to identify them.

When we are in the process of thinking about new procedures or new regulations, they are put on a list so that they get copies of any regulations which we might be promulgating in order to give them the opportunity to comment.

NEED FOR ATTORNEYS

Senator HARKIN. Senator Burdick?

Senator BURDICK. Ms. Dotson, in listening to your testimony you said you reduced your lawyer's staff because they weren't doing law work. Do you have a lawyer who is going out and doing investigative work, interviewing witnesses, and things like that?

Ms. DOTSON. When I first came on board I found that many of the legal counsel, which were being paid for out of the OCR budget, particularly in the regional offices, were not doing 100 percent legal work. And in some instances they might have been helping out the legal

services in another part of HHS but not doing Office for Civil Rights work specifically.

Senator BURDICK. They were lawyers but they weren't doing lawyer work, is that what you are telling me? Do you think you have an adequate legal staff now?

Ms. DOTSON. Yes; I do.

Senator BURDICK. They take care of everything that needs to be taken care of?

Ms. DOTSON. I have no reason to be dissatisfied with them. I get prompt replies to my questions and we work very harmoniously.

Senator BURDICK. You don't send them out now as insurance investigators as had been done, is that right?

Ms. DOTSON. You said we sent them out as insurance investigators. But——

Senator BURDICK. Well, that's what these people do.

Ms. DOTSON. The ones that are present in the regions now, I think it is a pretty fair statement to say that they are doing my work.

Senator BURDICK. I think it is a very important program and you need lawyers. But you need lawyers doing the right kind of work.

Ms. DOTSON. But we haven't reduced our headquarters contingent, and our headquarters contingent to me is the most important so that we are able to maintain consistency in what we do.

Senator BURDICK. I hope you keep the lawyers working doing what they are supposed to be doing and not running around the country chasing witnesses, which is somebody else's job, you know.

Ms. DOTSON. I am going to try to.

Senator BURDICK. Thank you.

PREPARED STATEMENT AND QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Ms. Dotson, there are a couple of other questions we have for the record, but we will send them to you and you can respond for the record. Thank you very much.

[The information follows:]

Statement of Betty Lou Dotson

I appreciate the opportunity to present the fiscal year 1987 budget request for the Office for Civil Rights (OCR).

OCR is requesting $19,285,000 in obligational authority, an increase of $145,000 compared to the sequestered FY 1986 amount. OCR's FY 1986 appropriation of $20,000,000 was reduced by $860,000 through sequestration. Of the total budget request, $15,285,000 would be provided in budget authority, together with $4,000,000 to be transferred from the Social Security and Hospital Insurance trust funds. This compares to $15,312,000 in budget authority and a transfer of $3,828,000, in FY 1986.

The budget request would provide 371 full-time equivalent (FTE) staff compared to 383 FTEs in FY 1986. This smaller staff size is consistent with the Administration's overall program to restrain spending and reduce the Federal deficit. Under this policy, OCR will achieve dollar savings throughout FY 1986 and FY 1987 through attrition, a closely controlled hiring policy, and management efficiencies, including space consolidation. These savings will enable OCR to absorb most inflationary cost increases in FY 1987. The nominal increase in the OCR budget request is mainly due to expected large increases in rental payments to the General Services Administration.

In FY 1987, OCR expects productivity increases to offset the FTE decrease. Year-end case inventories should not rise. OCR will continue to carry out an innovative, comprehensive, and effective compliance approach which includes investigations, reviews, voluntary compliance and outreach efforts. This approach is designed to ensure that the rights of HHS beneficiaries and potential beneficiaries are protected "proactively" and not solely by the "reactive" complaint activity. The FY 1987 budget for civil rights will maintain this forward momentum.

Compliance Responsibility

The mission of the Office for Civil Rights (OCR) is to eliminate unlawful discrimination and to ensure equal opportunities for the beneficiaries and potential beneficiaries of Federal financial assistance provided by the Department of Health and Human Services. OCR's objective is to accomplish its mission as effectively and efficiently as possible, with meaningful efforts to obtain voluntary compliance.

The Office for Civil Rights enforces various civil rights laws and regulations that prohibit discrimination on a variety of bases including race, color, national origin, handicap and age. OCR also enforces the community services assurance under which health care facilities assisted by the Hill-Burton Act must provide health care services to all persons residing and/or working in the service area without discrimination. Finally, OCR enforces the nondiscrimination provisions enacted under the health care and other block grants administered by the Department. On January 21, 1986, OCR published a proposed regulation to implement these provisions.

Compliance Activities

In fiscal year 1987, OCR will continue a pro-active compliance program designed to generate voluntary compliance on a wide scale among the Department's federally assisted programs and services. A total of 310 FTEs will be allocated to conduct reviews, monitor corrective action plans, carry out voluntary compliance and outreach activities, and to process discrimination complaints. These are the methods by which OCR follows up on information of alleged non-compliance and seeks to eliminate or prevent discrimination.

Reviews and Monitoring

To enforce the statutes and regulations, OCR periodically reviews the practices of recipients to determine whether or not patterns or practices of discrimination exist in Department-funded programs. Typically, OCR makes such assessments by conducting compliance reviews. OCR also conducts project reviews to follow up on specific compliance issues that have come to our attention through analyses of survey data or other compliance information. OCR plans to conduct approximately 633 compliance and project reviews in FY 1987. The number of comprehensive compliance reviews to be started will increase in both FY 1986 and FY 1987 from actual FY 1985 new starts.

OCR also conducts pre-grant reviews when notified by the Health Care Financing Administration that a health care facility has applied to participate in the Medicare program and must receive civil rights clearance. Approximately 3,000 pre-grant reviews will be completed in FY 1987.

If a review reveals or substantiates a compliance problem, OCR requires the program recipient to adopt and implement corrective measures. In addition, by means of written agreements, facilities subject to pre-grant reviews may be required to submit compliance information. Corrective action plans and agreements are monitored by OCR to assure full compliance. In FY 1987, OCR anticipates monitoring approximately 1,235 plans and agreements.

Voluntary Compliance and Outreach

The goal of OCR's voluntary compliance activity is to assist recipients in complying voluntarily with the requirements of civil rights laws and regulations in the most cost-effective way. Regional voluntary compliance and outreach staff directly provide technical assistance to recipient institutions, state and local agencies. OCR's voluntary compliance initiatives have included working with state and local agencies on aging to increase their ability to reach minority and handicapped older Americans. Recent reports indicate, for example, that one participating southwestern state increased minority participation in aging programs by more than 20 percent.

Under our outreach effort, OCR seeks to help beneficiaries and potential beneficiaries of HHS-funded programs to understand their rights and responsibilities under applicable civil rights laws and regulations, and to stimulate their participation in voluntary

compliance-related activities of recipient institutions. For example, OCR has trained leaders of refugee groups on the rights of persons of limited English-speaking ability, enabling recently resettled refugees to obtain nondiscriminatory health care services.

In FY 1987, OCR will continue and build upon successful voluntary compliance and outreach models. OCR will furnish technical assistance and compliance information to program recipients and beneficiaries through special projects, training, on-site consultations, conferences, and other contacts.

Complaint Investigations

Under the regulations implementing civil rights statutes, OCR is required to address discrimination complaints involving HHS programs in a timely manner. In addition, the Department of Justice, pursuant to their authority under Executive Order 12250, requires that each compliance agency such as OCR have procedures to resolve discrimination complaints promptly.

OCR expects to receive about 1,170 new complaints in fiscal year 1987, a small increase from the FY 1986 estimate. The 112 FTEs assigned to this activity will be adequate to process the complaint workload and reduce the year-end inventory.

Legal Services

OCR's budget request includes 27 FTEs to staff the Civil Rights Division of the Department's Office of the General Counsel, one FTE below the revised FY 1986 level.

OCR anticipates that the staff attorneys in the Civil Rights Division will be able to provide OCR with all necessary legal assistance and advice including: (1) interpreting statutes and regulations with which OCR must comply; (2) interpreting court decisions; and (3) when appropriate, conducting enforcement proceedings and referring cases to the Department of Justice.

Program Management

In fiscal year 1987, OCR will allocate 34 FTEs to program management, a decrease of two FTEs from FY 1986. This level is more than 20 percent below actual FY 1985 use and reflects OCR's commitment to reduce administrative and management staff to a bare minimum. OCR's commitment to strengthen compliance program staffing while reducing administrative and management staff was shown by the voluntary reassignment of approximately 10 headquarters staff members to regional offices during FY 1986.

Management staff determine program objectives and priorities, formulate and execute the OCR budget, monitor and evaluate compliance efforts, and make final decisions about OCR's compliance standards and procedures.

In addition, management staff provide administrative support in such areas as personnel management; travel; procurement; and, management of ADP, property, and supply systems.

Conclusion

In conclusion, Mr. Chairman, OCR's fiscal year 1987 budget request would provide 371 FTEs and $15,285,000, together with $4,000,000 to be transferred from the Social Security and Hospital Insurance trust funds. We believe this budget will enable OCR to maintain its program priorities and conduct an effective compliance program.

Biography of Betty Lou Dotson

Position: Director, Office for Civil Rights
Special Assistant to the Secretary
for Civil Rights
Department of Health and Human Services

Former Positions: Ms. Dotson began her Federal Service in 1956 with the Social Security Administration and served with the Department of Agriculture as: Director of the Civil Rights Staff, Food and Nutrition Service; Assistant to the Director of Equal Opportunity at the Department level; and most recently, Chief of the Adjudications and Complaint Division, Office of Equal Opportunity. She also served as Assistant Director for Equal Opportunity at ACTION from 1975 through 1978.

During 1979 - 1980, Ms. Dotson served at the Joint Center for Political Studies on an Intergovernmental Personnel Act assignment.

Ms. Dotson has more than 20 years of experience in the legal and social services area. Early in her career, she worked in the legal services trust department of the First National Bank of Chicago and for Chicago's Community Legal Counsel. She has been a caseworker for the Cook County Department of Public Welfare.

Education: Ms. Dotson graduated in 1950 from Ohio Wesleyan University with a Bachelor of Arts Degree in Political Science. She earned her J.D. degree from the Lincoln University School of Law in 1954.

Personal: Born in Chicago, Illinois Ms. Dotson currently resides in Washington, D.C. Because of her commitment to the special needs of young women, Ms. Dotson has been active in YWCA volunteer work for many years. She serves as a member of the Board of Directors of the National Capital area YWCA.

Questions Submitted by the Subcommittee

COMPLIANCE REVIEWS

Question. You have indicated that you have been able to enforce civil rights laws under your jurisdiction by increasing compliance reviews. How many compliance reviews were conducted in 1985, and of that number, how many were found to be out of compliance?

Answer. Of 135 compliance reviews completed during fiscal year 1985, 84 required corrective action.

Question. How do you bring an agency or institution back into compliance, and how long does that process take?

Answer. OCR works with recipients found to be in noncompliance to develop and implement corrective action plans. In many cases, a recipient will initiate and complete corrective actions before OCR makes a formal finding of noncompliance. In other cases, a corrective action plan is negotiated as result of a written letter notifying a recipient of its noncompliance status.

In fiscal year 1985, the average compliance review was completed in 289 days.

COMPLAINT INVESTIGATIONS

Question. You state that you will close more cases in FY 1987. How do you expect to accomplish this with a reduction in staff?

Answer. We expect to close approximately the same number of complaints (1,180) in both fiscal year 1986 and fiscal year 1987. We anticipate increases in staff productivity which will enable OCR to process complaints during fiscal year 1987 with two fewer FTE than during fiscal year 1986.

BLOCK GRANT COMPLIANCE PROCEDURES

Question. Are there any problems in monitoring the civil rights compliance of recipients of HHS funds under block grant programs that you do not have in monitoring categorical programs?

Answer. There are major differences in the block grant investigative and compliance review process as compared to the categorical process. However, in the enforcement process, the statutes require that the Governor be given a period of 60 days to secure corrective action whenever OCR finds there is noncompliance by a recipient of block grant funds. While this is not a problem, it was necessary to develop special procedures to facilitate this block grant requirement. The procedures are in place and no problems have been encountered.

Questions Submitted by Senator William Proxmire

BLOCK GRANT REGULATIONS

Question. I'm delighted to learn that, at long last, you have published a proposed regulation to implement the nondiscrimination provisions enacted under the civil rights portions of the block grant statutes. As you indicated last year, the draft regulations were first issued by your office in February of 1983. Can you tell the Committee when these regulations will take effect?

Answer. The Notice of Proposed Rulemaking (NPRM) was published on January 21, 1986. The 60-day comment period ends on March 24. While we cannot predict a precise date for publication of the final regulation, we are taking steps to expedite the analysis of all comments received. Based on the analysis, appropriate revisions will be made and the final regulation will be resubmitted through the regulatory clearance process.

PRE-GRANT REVIEWS

Question. I notice there has been a sharp fall-off in your pre-grant review workload as projected last year. In last year's justification you expected to perform 3,500 new reviews in both 1985 and 1986. This year's justification indicates that you performed only 3,067 new pre-grant reviews in 1985 and expect to perform 3,000 in 1986. Why were your initial projections so wide of the mark?

Answer. In the increasingly competitive health care industry it is difficult to predict how many new providers will seek certification and how many changes in ownership will require re-certification for the Medicare program. Our initial projections of the pre-grant review workload anticipated growth in the number of home health agencies, ambulatory surgery centers, and hospices seeking Medicare certification. The earlier estimates projected that most hospices would seek certification. In fact, however, as of the end of 1985 only 245 of approximately 1,500 hospices were Medicare-certified. Our current estimates of pre-grant review workload take the lower than anticipated Medicare-certified hospice growth rate into account.

GRADE CREEP

Question. I note that the average GS grade in your office is increasing. Last year you estimated the average grade in FY 1986 would be 10.65. You have since revised that upward to 10.84 and expect an average grade next year of 11.14. Can you tell us what is causing this grade creep?

Answer. A combination of reduced staffing, constrained hiring and the comparatively low grades of persons leaving OCR has led to a small increase in the average grade of OCR's staff.

CENTERS FOR DISEASE CONTROL

STATEMENT OF DR. JAMES O. MASON, DIRECTOR

ACCOMPANIED BY CLAUDE F. PICKELSIMER, JR., DIRECTOR, FINANCIAL MANAGEMENT OFFICE

INTRODUCTION OF ASSOCIATE

Senator HARKIN. Next we will hear testimony from Dr. James Mason, Director of the Centers for Disease Control [CDC]. The Centers for Disease Control performs a very important function in all of our health efforts. It is the responsibility of the CDC to protect our people from the ravages of disease and disability.

Dr. Mason, welcome to the committee. We are anxious to hear your statement. Please introduce whoever you have with you, and please proceed as you wish.

Dr. MASON. Thank you, Mr. Chairman. I am accompanied by Claude F. Pickelsimer, Jr., Director of the Financial Management Office of the Centers for Disease Control. We appreciate this opportunity to support the 1987 budget request for the Centers for Disease Control.

As you know, CDC's overriding goal is prevention of unnecessary illness and premature death. During the past 18 months we have reexamined our Nation's health problems with the specific goal of identifying those areas in which there are significant opportunities to improve the health of the people of this country.

Our fiscal year 1987 budget concentrates not only on the important things we have been doing in the past but will enable us to look even further at the reduction of infant mortality by deterring smoking during pregnancy, the prevention of invasive cervical cancer, and the prevention of injuries for older adults and minority groups.

Our strategy for the future is to maintain our current expertise and prevention of a diverse array of problems while focusing on those new challenges, to the extent possible.

Very briefly I will highlight a few of CDC's recent achievements and contributions to the application of public health practice at the community level. The first chart that I would like to highlight is on AIDS, which continues to be the Nation's most visible health problem.

We now have more than 18,000 cases reported and more than 9,500 deaths. That is about double the number of cases and deaths that we reported to this committee 1 year ago at the appropriation hearings. During the past year we have taken extensive actions to protect the Nation's blood supply, we have developed a national plan for AIDS

prevention and control, supported community-based risk reduction projects, and we have issued a series of national guidelines in several critical areas.

Apart from AIDS, infectious diseases are among the greatest causes of morbidity in the United States. Our programs include grants to States for immunization and sexually transmitted disease [STD] control activities, epidemiology surveillance, laboratory research, and in 1985 we maintained immunization coverage at record high levels and the incidence of childhood diseases remained at record lows.

For example, the second chart shows cases of measles were below 3,000 cases for the fourth straight year, despite importations and pockets of susceptibles that have prevented us from eliminating indigenous transmission altogether.

Support for State and local STD programs prevented an estimated 171,000 new gonorrhea infections and 5,500 syphilis infections.

The third chart shows primary and secondary syphilis morbidity. It decreased by 9.4 percent in 1985, the third consecutive year the rate has decreased.

Much work remains to be done to control infectious diseases, particularly in the areas of chlamydial control and prevention and control of hepatitis B. We are also working with State and local health departments and private practitioners to promote adoption of the national recommendations for adult immunizations and the use of *Haemophilus influenzae* b vaccine for children.

With the same fervor and expertise that we use to attack infectious diseases, CDC is tackling chronic diseases and environmental health problems. Heart disease and cancer combined contribute to over 3.3 million years of potential life lost annually. Unintentional injuries cause 3.4 million years of potential life lost, more than any other single health problem.

Problems of this magnitude are no longer acceptable because public health interventions are available or can be developed to prevent chronic conditions and their consequences.

Chart four shows our evaluation of a community exercise program on the Zuni Indian Reservation. The program demonstrated significant health benefits for diabetics who participated. For 2 years, the average weight loss among participants was 9 pounds, compared with 2 pounds among nonparticipants.

More significantly, 29 percent of the participants no longer require insulin or other drugs to control their blood sugar, as compared to 3 percent of the nonparticipants. Our strategy in health promotion and chronic disease prevention is to work closely with the National Institutes of Health and State and local health departments to assist in translating research into public health approaches that can significantly reduce chronic diseases.

With regard to occupational safety and health, we remind the committee that each year about 1 out of every 10 workers in private industry suffers an occupational injury. About 4 out of every 100 workers

are disabled, and about 7 out of every 10,000 workers are killed on the job.

Chart five shows the 10 leading causes of work-related diseases and injuries as identified by the National Institute for Occupational Safety and Health.

Senator HARKIN. Are those in order?

Dr. MASON. They are basically in priority order. All of those 10 would be called high priorities. They are taken from a list of 60 or 70 classifications, so we would say those are the 10 most wanted men in terms of the whole list.

During 1985 we convened a national conference of leaders in industry, labor unions, health professional organizations, and academia to develop strategies to address the first five of these problems. We will address the second five during this fiscal year.

For infant health, our fiscal year 1987 budget request includes $1.7 million for the CDC components of the Public Health Service infant health initiative, and we hope, thereby, to ensure infants a healthy start in life, which is one of CDC's high priorities.

There has been extensive public concern about the disparities in rates of infant mortality and low birth weight between blacks and whites. Because the etiology of these problems is complex, there are unfortunately no simple solutions.

For example, even when factors such as education that are related to economic status are controlled, infants born to black women still have twice the risk of being low birth weight and dying during the first year of life.

This chart shows risk of low birth weight is strongly associated with preventable maternal behaviors during pregnancy such as the use of cigarettes and alcohol and poor nutrition. In Missouri we found that regardless of other risk factors, smoking doubles the risk of low birth weight. For very high risk groups, infants whose mothers also smoke have a 25-percent chance of being born with low birth weight. This is one of the key areas that States will be addressing through the initiative that I described.

CDC's total request for fiscal year 1987 is $379.8 million. We are also requesting 4,015 FTE's, which includes 339 reimbursable FTE's. The revised fiscal year 1986 budget request for CDC is $367.2 million, not including $50.3 million for AIDS budgeted in the Office of the Assistant Secretary for Health on a comparable basis.

I would be pleased to answer any questions from the committee.

Senator HARKIN. Dr. Mason, thank you for your testimony. We do have three or four questions.

Dr. Mason, at last year's budget hearing the committee appreciated your candor when you testified that you felt you needed a staffing level of 4,437 full-time equivalent positions for fiscal year 1986 and that this level could be supported with the amount requested by the President. In the conference report accompanying our bill for fiscal year 1986 we included language directing that "not less than 4,398 full-time equivalent positions be maintained."

Your budget documents, however, reflect an FTE level for fiscal year 1986 at only 4,015, and I note the same level is requested for fiscal year 1987. Why is the fiscal year 1986 full-time equivalent level so far below the level you felt you needed to carry out CDC's activities, as well as being far below the level directed in our conference report?

Senator SPECTER. Mr. Chairman, before the witness begins his answer, I wonder if I might submit some questions for the record? I regret that I cannot stay, but I would like to submit a few questions.

Senator HARKIN. Surely, Senator. Did you want to ask them right now?

Senator SPECTER. No; I just wanted to submit them for the record.

Senator HARKIN. Thank you.

Dr. MASON. The overriding reason for this reduction is the achievement of the President's objective to restrain Federal domestic employment.

Senator HARKIN. I am sorry, say that again, Dr. Mason.

Dr. MASON. The overriding reason for the reduction is the achievement of the President's objective to restrain Federal spending and Federal employment.

Senator HARKIN. Well, you said you needed this level, and you said that it could be supported with this amount requested by the President, and then we said it in our conference report. Now tell me again why we are almost 373 below that?

Dr. MASON. With sequestration and with other changes in our budget, I am sure that we could no longer afford that number of FTE's that were originally requested.

Senator HARKIN. This is significant. You are not talking about 10 or 20, you are talking about 300 and some people. You are talking about, I believe, a 10-percent cut, so something has got to happen.

What is the impact of this? What is being tightened down on? What isn't being done?

Dr. MASON. As we tighten our belts, what we are trying to achieve is to identify those areas of activity that may have been high priorities 10, 20, 30 years ago that in 1986 are not as high priority. We are scaling down, and sometimes eliminating, those whose job is now finished so we can concentrate the remaining FTE's and resources on problems that are of highest priority in the 1980's and early 1990's.

Senator HARKIN. What areas? Tell me, what areas are those? Can you tell me some areas that you say you are going to cut down on that were high priority in the past but are no longer high priority.

Dr. MASON. In 1967, for example, the Clinical Laboratory Improvement Act was passed, and we have now been working on that for 19 years to upgrade laboratory service. This was a responsibility to assist in upgrading the competency of laboratories that were operating in interstate commerce. In 20 years, as a result of the Federal activities, those laboratories are obtaining a much better level of performance than they were 20 years ago. We can begin to turn this responsibility over to the private sector, the American College of Pathologists, the American As-

sociation of Bioanalysts, and others that can do the work. Then we can take FTE's that were doing proficiency testing and carrying out other activities that can be assumed by the private sector and put them into the forefront of some of the things that I have talked about in chronic disease, immunization, and other new opportunities.

Senator HARKIN. OK, that is one. How many FTE's would have been involved in that clinical laboratory improvement?

Dr. MASON. Well, as an illustration, probably in the range of 25-30 FTE's that we will gain that we can put in more meaningful projects. That is basically what we are trying to do.

Senator HARKIN. So there are about 10 of these different programs? Because again we are talking about 300 and some people.

Dr. MASON. I am not sure it will come up with the total of 300, but I am giving you the philosophy that we are trying to follow.

Senator HARKIN. Again, you can always point to one program, and perhaps you are right, I don't know. Perhaps there is something that you can cut back. I don't know. If you are talking about cutting 25 or 30 people, or 40, you can say that. But, again, we are talking about almost a 10-percent cut and you would have to come up with an awful lot of those programs to justify that kind of a cut.

I would like to ask you to submit for the record those areas that you just mentioned that you thought were high priority in the past that you can cut down on. Give me the number of FTE's that are being eliminated and could possibly be shifted to some of the areas that you now consider to be high priority.

Dr. MASON. We would be delighted to do that.

[The information follows:]

FTE REDUCTION FROM CONGRESSIONAL ALLOWANCE

	1987 appropriation	1987 revised	Reduction
Preventive health block grants	73	48	-25
Sexually transmitted diseases	621	555	-66
Immunization	216	197	-19
Infectious diseases	753	713	-40
Chronic and environmental disease prevention	489	426	-63
Occupational safety and health	853	806	-47
Epidemic services	945	863	-82
Program management	81	68	-13
Reimbursable	367	339	-28
Total	4,398	4,015	-383

FULL-TIME EQUIVALENT REDUCTION FROM BUDGET REQUEST

Senator HARKIN. Just to see what that mix looks like.

Dr. MASON. All right, fine.

Senator HARKIN. How many FTE's did you originally ask the OMB for?

Dr. MASON. Our request to OMB was for 4,265.

Senator HARKIN. For next year?

Dr. MASON. For fiscal year 1987.

Senator HARKIN. For fiscal year 1987. So what you are going to get is 4,015. So, again, that is 5 percent less than what you requested. Again, I would like to know how you are going to meet the needs out there with that kind of a cut from what you originally asked for.

Evidently what you asked OMB for was even less than what you said you needed before.

Dr. MASON. That's correct.

Senator HARKIN. That's correct. Again, I raise the question of how much you can tighten down on some of these other programs to get to that 4,015 level. But, you will submit that for the record, so we can take a look at it.

Dr. MASON. We will be glad to do that.

[The information follows:]

FTE REDUCTION FROM BUDGET REQUEST

	1987 OMB request	1987 President's budget	Reduction
Preventive health block grants	73	48	-25
Sexually transmitted diseases	624	555	-69
Immunization	218	197	-21
Infectious diseases	704	713	+9
Chronic and environmental disease prevention	478	426	-52
Occupational safety and health	839	806	-33
Epidemic services	899	863	-36
Program management	81	68	-13
Reimbursable	349	339	-10
Total	4,265	4,015	-250

ORIGINAL BUDGET SUBMISSION

Senator HARKIN. At this point I would also like to ask what was your original fiscal year 1987 budget request that you submitted to the Secretary?

Dr. MASON. In our original submission we asked for a total of $537,618,000. I should explain that AIDS is now being handled out of the Office of the Assistant Secretary for Health and that accounts for $45 million of the difference, and then the facilities that we ultimately will need at CDC was for another $50 million, so that at least $95 million of that was for buildings and AIDS. AIDS is now placed somewhere else.

Senator HARKIN. So let's just say $100 million just to round it off. Out of $537 million, that would cut it down to $437 million. And now it looks like we are going to get $379.8 or $380 million, so that it looks like some $60 million less.

Dr. MASON. That is correct.

Senator HARKIN. $60 million, so that is over a 10-percent cut. It is well over 10 percent, maybe a 12-percent cut.

Do we have, for example, from your original request to the Secretary, a breakdown so we can see what areas are cut—we don't have it?

I would like to ask that for the record you provide us with a breakdown so we can compare what we are getting and where we see the cuts coming. Do you understand what I mean?

Dr. MASON. Absolutely.

[The information follows:]

REDUCTIONS FROM BUDGET REQUEST

	1987 request	1987 President's budget	Reduction
Preventive health block grants	$93,273,000	$89,525,000	-$3,748,000
Sexually transmitted diseases	63,802,000	55,453,000	-8,349,000
Immunization	76,121,000	56,012,000	-20,109,000
Infectious diseases	83,075,000	36,358,000	-46,717,000
Chronic and environmental disease prevention	38,743,000	24,425,000	-14,318,000
Occupational safety and health	64,571,000	60,036,000	-4,535,000
Epidemic services	62,920,000	53,131,000	-9,789,000
Buildings and facilities	51,910,000	1,810,000	-50,100,000
Program management	3,203,000	3,096,000	-107,000
Total	537,618,000	379,846,000	-157,772,000

[1] Includes reduction of $45,800,000 resulting from transfer of AIDS Program to the Office of Assistant Secretary for Health in 1987 President's budget.

CHILDHOOD IMMUNIZATION

Senator HARKIN. I may want to get back to Gramm-Rudman, but I do have something else I want to ask on the childhood immunization. Last year you described a series of factors leading to a shortage of diphtheria, tetanus, and pertussis [DTP] vaccine causing you to recommend postponement of the fourth and fifth doses for children to prevent an acute shortage.

You testified last year that you expected to have inventories replenished by the end of fiscal year 1985 so that you could begin recalling children who had missed their fourth and fifth doses.

Dr. MASON. That is correct.

Senator HARKIN. So I am clear on that.

Dr. MASON. Right.

Senator HARKIN. Again, has this happened?

Dr. MASON. That has happened. The shortage was caused by manufacturers and distributors dropping out of the marketplace and then some lots that were produced and voluntarily withheld from the market on the part of the manufacturer. For those reasons we had a temporary shortage of DTP that resulted in the recommendation not to give the last two doses. There is no longer a shortage at this point in time and we have gone back and immunized those children that were missed.

But I don't want to leave you with the impression that this problem is necessarily solved. I think we are staring a crisis in the face as we approach this summer again, unfortunately.

Senator HARKIN. Now let's get this clear. You say the DTP supply is OK right now.

Dr. MASON. It's OK right now.

Senator HARKIN. You have gotten the recall of the children all basically up to date.

Dr. MASON. That's right.

Senator HARKIN. For the fourth and fifth doses.

Dr. MASON. That's right.

Senator HARKIN. And so they have completed the required doses.

Dr. MASON. That's right.

Senator HARKIN. But you say you are staring at a crisis because of this summer. Tell me more about that.

Dr. MASON. We are very concerned because of the reinsurance problem that the existing manufacturers are facing. There are two manufacturers of DTP, actually three manufacturers, and two who sell it. Those two who are selling will have to reinsure between now and June 30. One manufacturer has their reinsurance expiring at the end of March, and the other one expires at the end of June.

If one or more of those were unable to reinsure, they may decide not to sell vaccine.

Senator HARKIN. You are talking about liability insurance?

Dr. MASON. That's right.

Senator HARKIN. There are three manufacturers of DTP, two suppliers.

Dr. MASON. That's right. Wyeth, Connaught, and Lederle. Lederle both manufacturers and sells their own plus Wyeth's. Wyeth doesn't want to get into the problem of liability insurance, either they don't have it or don't want to get it, so their product DTP is distributed through Lederle.

Connaught is due to have their insurance, as we understand it from the company, expire by the middle of April. Lederle's will expire on June 30. At least Lederle's production is dependent upon—not production, but their continued sale of vaccine is dependent upon their being able to get reinsurance.

We have contracted for 4 million doses of DTP for the stockpile, which would help avoid a problem for a few months. But we are talking about basic serious problems in terms of availability.

Senator HARKIN. Dr. Mason, staff has just informed me that this year's budget does not request any funds to maintain an adequate stockpile of vaccines.

Dr. MASON. It's correct that the fiscal year 1987 request does not include money for further expansion of the stockpile.

Senator HARKIN. Can I walk through this with you? What is the purpose of the stockpile?

Dr. MASON. The stockpile was designed at a time when we had no more than one vaccine manufacturer selling or producing vaccine. Even in the best of circumstances, occasionally you will produce a batch that will not meet the food and drug requirements, so that batch has to be set aside and a new one produced.

With single manufacturers of oral polio, measles, mumps, and rubella, we wanted to be sure that if there were one or more bad batches that would never be marketed, would never meet the criteria to be marketed, that there would be vaccine stockpiled so that we could continue to immunize with no interruptions until a new batch could be produced and distributed.

Senator HARKIN. So there are two reasons for the stockpile. One is in case of production stoppage or something like that, the second is obviously in case of an epidemic.

Dr. MASON. Yes; and probably a lesser need, because if you have got continued production and all your kids are immunized, you shouldn't have an epidemic.

Senator HARKIN. Is it true that the Department has a previously stated goal of maintaining a 6-month stockpile?

Dr. MASON. That has been the goal.

Senator HARKIN. And how much do we have now?

Dr. MASON. We have two-thirds of a 6-month stockpile about 17 weeks.

Senator HARKIN. So if they stop manufacturing it, you are saying that that stockpile will dwindle rapidly, is that right?

Dr. MASON. That's right. But the stockpile was never designed to handle the crisis that is staring us in the face, and that is the crisis of litigation, liability, and unpredictable costs of liability. Insurance companies can no longer predict what their premium should be.

Senator HARKIN. Let me just ask you, to cut through this, there is no request in the budget, right? No request in the budget. It has been funded at an annual level of $4 million in each of the past few years. There is no request to maintain it, yet you say we are facing this crisis. That doesn't seem to add up.

Dr. MASON. A stockpile won't even begin to solve the crisis. A stockpile is designed to get us by for a few months while the litigation-liability-compensation issue could tie this Nation up for a much longer period of time than that. We have got to go for more fundamental solutions to that problem than a stockpile.

Senator HARKIN. Let me ask you this. Did you originally ask for stockpile funds in the original request to OMB?

Dr. MASON. Yes.

Senator HARKIN. Why?

Dr. MASON. The stockpile is to help us in case there is a production delay due to batches of vaccine that don't meet the requirements. We would still like to get that to 26 weeks. Right now we have two distributors of DTP, we have other manufacturers seemingly coming into the market, so the need for the stockpile seemed to be less right now than getting down to the root cause of the liability issue.

Senator HARKIN. It just seems to me, Dr. Mason, that the stockpile has been funded in the past, a previously stated goal of maintaining a 6-month stockpile. Has it ever been more than that?

Dr. MASON. No; we have never gotten up to the goal of 6 months.

Senator HARKIN. Even if you had 6 months stockpiled, and obviously the experts, the people who understand the need for this—you, Dr. Mason, you are a doctor—you have requested this.

Dr. MASON. I agree, it would be good to have a 6-month stockpile.

Senator HARKIN. Somebody cut it out. Somebody at OMB obviously has cut it out.

Dr. MASON. There are some reasons for cutting it out. First of all, we hope to have a better DTP vaccine, an acellular vaccine, so it makes little real sense to have a stockpile of vaccine that may be obsolete.

Senator HARKIN. When are you going to have this? You say you hope to have it.

Dr. MASON. We are talking about 2 or 3 years before that——

Senator HARKIN. My God, we are talking about a 6-month stockpile that won't be there even for this year.

Dr. MASON. I agree. It would be comfortable to have a 6-months stockpile.

Senator HARKIN. I would think so. I understand what you are saying about the reinsurance problem and that it may take longer than 6 months. But even if we do bump up against that kind of a problem, with the reinsurance problem with some of these laboratories, it still would be nice to have a 6-month stockpile there as a buffer.

We may get something in 6 months, there may be something that might take place at the Federal level in terms of legislation. There are two or three different approaches being taken at the Federal level.

But it seems to me very shortsighted if we just said we are going to cut this. If we run out of the stockpile, we face a crisis this summer and yet the Congress addresses this issue prior to the end of the year.

Dr. MASON. Congress really needs to address the liability issue. That is where our greatest potential for problems comes. What are we going to do about the problem?

Senator HARKIN. It just seems to me a very inexpensive insurance policy. We are talking about $4 million, is that what it was?

Dr. MASON. That won't get us a 6-months supply, but that would add to our supply.

Senator HARKIN. What would get us the 6 months?

Dr. MASON. The cost of vaccines is going up so rapidly—unless Claude has a figure. What is it? About $19 million would be required to get all of the childhood vaccines up to 6 months.

Senator HARKIN. You say you have 18 weeks now. It won't cost you $19 million to go from the 18 weeks to the full 24 weeks.

Dr. MASON. For all of the antigens it would.

Senator HARKIN. Wait a minute, that can't be right. You say we have an 18-week supply now.

Dr. MASON. Right.

Senator HARKIN. You want to go to——

Dr. MASON. Twenty-six weeks.

Senator HARKIN [continuing]. If I am not mistaken, 6 times 4 is 24, or 26 weeks. And you are saying it is going to cost $19 million to go from 18 to 26 weeks?

Dr. MASON. That's right. The cost of vaccines, DTP vaccine has gone up, since 1982, about 4,000 percent. Oral polio and MMR are going up at staggering rates, and it has become very, very expensive to buy vaccines today. A 94-percent increase in polio in just 1 year.

Senator HARKIN. A 94 percent increase in the cost of the polio vaccine in 1 year? Is this because of the insurance problem?

Dr. MASON. There are many reasons, but that is the major one. If that one is solved, I think we would stabilize.

Senator HARKIN. How many manufacturers are there of oral polio vaccine at the present time?

Dr. MASON. One at the present time, and another is applying for a license.

Senator HARKIN. There is one manufacturer and they have increased their prices 94 percent.

Dr. MASON. In 1 year.

Senator HARKIN. Who is the manufacturer?

Dr. MASON. Lederle.

Senator HARKIN. Something isn't right there. Ninety-four percent. I would like to see some justification for that.

I think we have just about covered the issue of the stockpile. From what I understand, you do see a need for it obviously; you requested money for it. But somebody cut it out at OMB. I think you agree that it is needed.

Now, on behalf of Senator Inouye I would like to present this question to you. Representative Waxman and Senator Inouye are concerned about the effect your proposed budget would have on our Nation's children and particularly your immunization program.

It is our understanding that at the present time the various States have had the option, and the Federal resources, to either purchase necessary vaccine from CDC or, in the alternative, to use funds under this program to hire necessary staff, such as public health nurses. We are concerned that under your proposed budget there will not be sufficient resources to ensure our Nation's children will receive adequate protection. We would appreciate your comments and in particular whether you believe the States will be able to continue to have this option.

Dr. MASON. In the fiscal year 1987 budget we will be able to provide a comparable number of doses of the oral polio vaccine and mumps, rubella, and measles vaccine as in the previous years. This will expend about $32 million. It will allow about $14 million to be left over to be used at the option of the States.

With that $14 million, they can either use it for program operations, which would include their own employees, assignment of CDC employees, or they can buy DTP vaccine, or they could even buy the new *Haemophilus influenzae* b vaccine. So the $14 million can be used at their discretion.

Senator HARKIN. How much more would it cost to fund both the continued Federal portion of the DTP purchases and the State administration of the vaccine program?

Dr. MASON. If we were to go at the same level as fiscal year 1985 it would require a total of about $67.9 million for vaccine and program operations.

Senator HARKIN. $67.9 million. That would be to continue to fund both the Federal share of the vaccine purchases and the State administration of the program.

Dr. MASON. That is right. That level is comparable with fiscal year 1985.

Senator HARKIN. $67.9 million more?

Dr. MASON. No; that is the total.

Senator HARKIN. $10 million more that's in the budget. What did you request?

Mr. PICKELSIMER. $47.7 million.

Dr. MASON. There are CDC program operations and one figure that you may be——

Senator HARKIN. So $50 million is the total, what you requested, right?

Mr. PICKELSIMER. When you are just comparing the grant operations which the States get, it is $47.66 million, so it is about a $20 million difference.

Senator HARKIN. Let me get this clear. You said you needed a total of $67.9 million, and that is for the Federal share——

Mr. PICKELSIMER. For the grant operation.

Senator HARKIN. And the administration, that is together.

Mr. PICKELSIMER. Yes, sir.

Senator HARKIN. I see. So it is $20 million there?

Mr. PICKELSIMER. That's right, and to maintain the 1986 level would be $11 million.

Dr. MASON. The reason for that shortage is the escalating cost of those vaccines. We need to stabilize those costs.

Senator HARKIN. We seem to be in a bit of a bind here. I understand what you are saying, but if the vaccines are not being delivered out to the States and we aren't providing for the administration of them, that means children are not being immunized. Is this the crisis you are talking about looming ahead?

Dr. MASON. The children are being immunized at the present time. But if we can't get manufacturers to sell that vaccine because they can't reinsure, then we can't maintain their immunization levels. There is no question under the fiscal year 1987 budget that the States are going to have to put more State money in to maintain the public supply of vaccine. There is no question about that.

But we anticipate that the States will increase their ante into the program so that immunization levels will be maintained.

Senator HARKIN. Will the States do this? Do you know that they will do this? Do they have the money to do it? Have they indicated to you they will?

Dr. MASON. Some States indicate they will, others are questionable.

Senator HARKIN. It just seems to me that you are talking about $20 million less than what you say is needed for levels comparable to last year. It seems to me that even if the manufacturers continue to manufacture, there are some States that maybe could pick up the difference, but there are a lot of States that are really strapped right now. I can tell you about one, where I am from.

Again, someone in OMB is cutting money out without really understanding what in the heck is going to happen this summer when these kids aren't immunized.

Do you share that at all?

Dr. MASON. Obviously there are concerns that we must maintain immunization levels in the United States. We have achieved levels of immunization and reduction in disease that have never occurred before and we need to stay there.

Senator HARKIN. This seems to be an awful retreat from that. When you cut $20 million out of $60 million, that is a big cut. It is a one-third cut. I don't know that the States can pick that up.

Senator Chiles?

Senator CHILES. Thank you very much, Mr. Chairman. Dr. Mason, on the subject of designer drugs, the Attorney General recently reported to the Appropriations Committee the potential spread of this phenomenon across the country is a real possibility and a cause for serious concern. Based on what you learned from CDC's investigations in California, what is your judgment as to the potential public health consequences if this phenomenon was to spread across the country?

Dr. MASON. Senator Chiles, as you know, we have had problems associated with designer drugs already in California, Michigan, Texas, and in your own State of Florida, so if you put that on a map it is probably already spread across the country.

Senator CHILES. What do you see as the potential effects of that?

Dr. MASON. In terms of the seriousness of MPTP, limited numbers, but where they have developed all of the symptoms of Parkinson's disease, for those individuals, they are practically incapacitated. Although not a great number are involved today, the individual involvement is very serious, very severe, and of course, we need to prevent the spread of this kind of activity.

Senator CHILES. What specifically does the CDC plan to do with the additional $2 million appropriation provided in the 1986 bill, assuming Congress does not approve the proposed rescission?

Dr. MASON. First of all, I want to just mention that we see ADAMHA as having a major responsibility in this area, so CDC would be an associate with the National Institute of Drug Abuse in doing something about it. We have a six-point program of locating, interviewing, following-up, and examining persons; providing clinical toxicological services; creating working groups; evaluating MPTP-like compounds; developing a national drug program; and intervening.

The six-point program I think would do something about this, and as I say, it would be very cooperative with ADAMHA, who have prime responsibility for this area.

Senator CHILES. The clandestine manufacture of MPTP can result in the production of the byproduct MPTP if the synthesis is not carefully controlled, and then we know the MPTP produces the symptoms of Parkinson's disease. We also know that MPTP was recovered by the police in Fort Lauderdale and we know that you have a team in south Florida.

What incidents initially prompted CDC to go into Florida? Was it discovery of MPTP capsules or was there evidence of the use of MPTP with some resulting health problems?

Dr. MASON. We were invited by the Florida State Health Department who had identified, presumed that they had cases of Parkinson's disease related to the use of MPTP. So at their invitation, we have assisted them in looking into the problem, defining its magnitude, and identifying the sources of the production of this material.

Senator CHILES. Could you outline for me the approach being taken in south Florida? What types of personnel have been assigned and what they are looking for?

Dr. MASON. I can't give you specifics here. I would be happy to submit that for the record.

Senator CHILES. Can you give me a rough outline of what you have found so far indicating that designer drugs are in south Florida being used?

Dr. MASON. Yes; a drug has been distributed in south Florida, possibly since 1983. It is the designer drug, contaminant. MPTP is a neurotoxin. It is an M-pyridine analog. It is like Demerol. In trying to synthetically produce Demerol in someone's lab, they just don't quality control it and you end up with this very, very neurotoxic substance contaminating it.

We have identified two intravenous drug users who have developed Parkinsonism. These have been confirmed by a neurologist. Several others have neurological symptoms and signs which are suggestive. We are very carefully, with the help of the clinicians that are needed in this process, observing, and trying to widen the net to bring in others that may have been exposed.

And then working again with the State of Florida we are trying to disseminate information, to not only potential drug abusers, but physicians, clinics, and hospitals. We are trying to get the warning out, that people ought to abstain from that kind of product.

Senator CHILES. I think that is tremendously important. This is what we started talking about in our hearings early on on this, to get the warning out before we have a disaster in Florida. We have got two cases now. We don't know how many are undiscovered. But if we could get the warning out so that people will understand.

I understand the investigative team, headed by Dr. Jim Ruttenberg, has been in Florida for 1 week or so, and that Dr. Ruttenberg will tell

us something of his findings during the meeting that I am going to hold in Fort Lauderdale Monday morning.

I want to thank you for making Dr. Ruttenberg available to us and for the work that you are doing on what I think is potentially a terrible, terrible problem. I think education is probably the best way we can deal with this one. I think we are going to have a hard time dealing with it from the enforcement side.

We have got to get out there on the education side. That means being able to convince people what the dangers are. The Parkinson's type paralysis, the results are just horrible. We thank you for the efforts.

Dr. MASON. CDC and NIDA will be there on Monday.

Senator CHILES. Thank you, sir. Thank you, Mr. Chairman.

Senator HARKIN. Do you expect to maintain the level of immunizations that we had last year if we don't have further input from the States? If the States don't fill in this gap.

Dr. MASON. We won't have epidemics the next day. It takes weeks, months, for susceptible populations to build up. But after a period of 6 months, you might expect increased cases of pertussis, and particularly, diphtheria. So indeed there are risks to allow groups of unimmunized people to build up.

Senator HARKIN. Again, for the record, I want to point out we are talking about immunization for poor children, children that come from low-income families. Now, barring a shutdown of the manufacturer of this, my kids that maybe have money, they can still go to their pediatrician for their immunization.

But the children of families that can't afford it, they are the ones that are cut off from it.

Dr. MASON. That is correct. It would be the public supply that——

Senator HARKIN. And they are the ones more often than not that are most susceptible to these diseases.

Dr. MASON. Anyone who isn't immunized is more susceptible.

Senator HARKIN. That's right. Poor children are in day care centers and places where disease can be transmitted rapidly.

Dr. MASON. That's right.

Senator HARKIN. I thank you for your forthrightness on this issue. I just can't believe that we are doing this when all of the cost-benefit ratios have been well documented. The benefit-cost ratio of rubella immunization given in combination with measles is estimated to be over 14:1, the benefit-cost ratio for polio 10:1. This translates to an estimated savings of about $1 billion per year and $500 million per year for measles.

Since 1963 over 59 million cases of measles and 19,500 cases of mental retardation have been averted, and 5,900 children's lives have been saved as a result of measles immunization.

That is from your justification of appropriations estimates.

Dr. MASON. That is correct.

Senator HARKIN. Well, we will see what we can do about that. Again, I appreciate your forthrightness. Let me just ask you a couple more questions on AIDS.

Dr. Mason, your fiscal year 1987 budget request proposed a 30-percent cut in AIDS funding from the level appropriated in fiscal year 1986. How do you justify this reduction?

Dr. MASON. I believe two are rescissions, one for the 24-hour hotline and the other was money for alternate testing sites, and that is basically the reduction.

Senator HARKIN. I am sorry.

Dr. MASON. It was a 24-hour hotline, about $2 million. The alternate test sites about $10 million. Then there was a one-time appropriation of $6.9 million for the provision of drugs that probably will be administered by NIH rather than us. We are working cooperatively with them.

Senator HARKIN. So the ones that wouldn't be continued would be the 24-hour hotline——

Dr. MASON. That's right. We have a hotline in many communities and one at CDC, but this was additional money that Congress had authorized.

Senator HARKIN. It was specifically put in by this subcommittee, right? Specifically.

Dr. MASON. That's correct.

Senator HARKIN. Dr. Mason, did you request cutting the hotline to OMB?

Dr. MASON. No.

Senator HARKIN. Has the hotline been used?

Dr. MASON. The hotline that CDC is carrying on is used, yes.

Senator HARKIN. So it didn't have a 24-hour hotline up to now, this is one that we put in for a 24-hour hotline.

Dr. MASON. That's right.

Senator HARKIN. How long is yours, is it 12 hour, 8 hour, or what?

Dr. MASON. It is during the working day, and then there is a recording device so that they can get a message 24 hours. But, if they want a specific callback to consult on a specific problem, then they have to wait until the daylight working hours. It is 5 days a week from 9 a.m. to 7 p.m. e.s.t.

Senator HARKIN. So the 24 hour one was 7 days a week. How much does it cost?

Dr. MASON. $2 million.

Senator HARKIN. $2 million, and that is proposed for rescission, and for cancellation in next year's budget. But you did not request that?

Dr. MASON. The CDC hotline that we are currently operating will continue as well as many private and public hotlines in various communities. I think there was a legitimate concern, that the best hotlines are in the communities, like New York City, Miami, San Francisco, Los Angeles, where they can address specific community problems, rather than a central operation. It was felt that we should encourage and help the communities to do their own 24-hour hotline, rather than having a central Federal one.

Senator HARKIN. That's true. People all over the country are getting AIDS, not just in some of those cities that you mentioned.

Dr. MASON. You are absolutely right. It isn't—there are concentrations of cases in some of these cities, but it is a national problem.

Senator HARKIN. It is a national problem and it is a disease, as you know, that can be transmitted and carried around the country. People are mobile, move around.

I am informed that the chairman of this subcommittee certainly will not approve the rescission and the cut for next year. Just for the record, I want you to know that he will have my support, too.

The fiscal year 1986 appropriation was $65 million. The fiscal year 1987 budget request is $45.8 million for AIDS activities at CDC. Again, that is a $20 million cut, a one-third cut in AIDS, and yet your chart shows the occurrence of AIDS going up, we are expecting more cases, and yet we are cutting it by one-third.

Dr. MASON. The alternate test sites were originally funded as one-time support to the States and communities to get local facilities going. They were never given with the understanding that this would be a continued grant program. So we hope that the initial $10 million that was funded in 1985 will provide an opportunity, or did provide, and now the States and local communities are building on that initial money that was given to them for alternative site development.

That was the philosophy. This was one-time money. The administration feels the local response should continue those.

Senator HARKIN. Has that happened? Are States doing that.?

Dr. MASON. In many communities. I can't say everywhere it has happened, but many communities have continued, and in fact, gone far beyond what was started through the alternative site funding.

Senator HARKIN. Again I would like to ask: Did you ask for funds to continue these?

Dr. MASON. I don't believe that was ever in our request.

Senator HARKIN. So the activity provided in the original fiscal year 1986 appropriation that would not be continued because of this $20 million cut is the 24-hour hotline?

Dr. MASON. That's right.

Senator HARKIN. The alternate sites. And you said something about a drug provision and I didn't understand what that was, but evidently you provided——

Dr. MASON. The provision here is that as NIH carries out its drug trials, if one of these drugs was found to be safe and significantly beneficial, it would be made available. There is a period of time between the licensing of the drug and the disclosure that the drug may be useful in treating patients, and since people can't buy it until it is licensed, and the manufacturers can't sell until it is licensed, we would provide it under an investigational new drug application. This was a one-time request of $6.9 million that would not be used until that point in time when it was needed to provide drugs for AIDS patients, until the firm producing the beneficial drug could get it licensed and on the market.

So we haven't used that. There has been no call for it because the drugs are still in the testing phase. That demand has not occurred and it is just sitting there like money in the bank to be used at that moment in time. So it hasn't been spent, and it would be carryover money until a drug has been proved safe and effective. It was an emergency stop-gap.

Senator HARKIN. This is my last question on AIDS, it may be my last question totally. How will centralizing AIDS funding under the Assistant Secretary for Health affect the AIDS-related activities of the CDC?

Dr. MASON. The AIDS czar is Dr. Walt Dowdle, who is part of CDC. We know that he is fair and will see that each of the agencies within the Public Health Service get their needed share. I don't see this as just up-for-grabs there. It is just a way to centralize.

As soon as the money is appropriated, we will get what is in our budget, and I have no concerns about the process.

Senator HARKIN. Regarding sexually transmitted diseases, the CDC's prevention efforts have been fairly successful in reducing the incidence of venereal disease in this country. I understand, however, that you have information that as a result of the Gramm-Rudman-Hollings cuts, you anticipate that fewer cases of gonorrhea will actually be prevented as the incidence of this disease increases.

Is this correct?

Dr. MASON. I am not sure that we can put a one-on-one basis——

Senator HARKIN. From your budget document, Dr. Mason, you have here under impact data, the number of gonorrhea cases prevented in 1985, 171,000, and in 1986, after sequestering, 138,000. Then it goes back up in 1987 to 150,000, but still a cut from 1985.

Dr. MASON. I am not sure the number of cases going down is because there are fewer cases or whether you can—we just felt that with trends of syphilis and gonorrhea, that we have pretty well maintained the same control activities. Whether there is an effect between dollar cuts and number of cases that will go down, it is hard to measure.

We do put in our charts that there will be fewer cases prevented, that is correct. But it is just as much that there are fewer cases to prevent.

Senator HARKIN. You have the same chart I am looking at, and you estimated morbidity levels, gonorrhea goes from 921,000 up to 958,000. So that is an increase.

Dr. MASON. Then in 1987 down to 939,000.

Senator HARKIN. But still an increase from 1985.

Dr. MASON. Well——

Senator HARKIN. Again, I think fewer cases will be prevented and we will have more cases of gonorrhea because of the cut in the funding. What was the cut in this anyway?

Dr. MASON. $2 million in the grant program.

Senator HARKIN. Yes; it is down again from last year quite a bit. Now, the committee has received information indicating that between 15 and 30 percent of sexually transmitted disease control funds, and as much as 45 percent of staff time has been devoted to the AIDS effort. Is this accurate?

Dr. MASON. I think when you say 45 percent of staff time, that is probably not accurate. If you had asked for numbers I would have said about 45 FTE's had been diverted out of several hundred, so it wouldn't be 45 percent.

But there is no question, that ever since the epidemic was first described in 1981, we have been loaning people from STD control to AIDS control. I think that is useful because these are the trained people who can work in both areas. As you control AIDS, you also control syphilis, you also control gonorrhea, so there is a direct relationship. I don't see us taking from Peter to pay Paul, I see a relationship there that is a reasonable one.

Senator HARKIN. Still, gonorrhea goes up.

Dr. MASON. There has been a slight increase.

Senator HARKIN. Again, I ask the question. I understand that there is some correlation, interrelationships between AIDS and other sexually transmitted diseases. But I do want to ask you if our funding level for the AIDS effort is so inadequate that we have to divert funds from the other sexually transmitted disease programs into AIDS, even though there is some interrelationship we do have to take some from the other programs to put into AIDS because our AIDS funding doesn't seem to be adequate.

Dr. MASON. It is more than a funding problem. It is the availability of trained people. Whether you are in the research laboratory or out in the field, you have to take people that are already up to speed, so we share the most qualified, the most expert people, and that is going on.

Mr. Pickelsimer just commented that we are just talking about CDC people, who are a small minority of the people that are assigned to this activity at the local level. All of the control work isn't done by CDC. In fact, the vast majority are State people, local people that are working in this effort.

Senator HARKIN. Dr. Mason, unless you have anything else you would like to say, I would like to thank you for your testimony, for being so forthright, and I appreciate it very much.

Dr. MASON. Thank you very much.

PREPARED STATEMENT AND QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you. There will be some additional questions which we will submit to you for your response for the record.

[The information follows:]

Statement of James O. Mason

Mr. Chairman and Members of the Committee: It is a pleasure to be here to support the 1987 budget request for the Centers for Disease Control (CDC).

CDC's overriding goal is prevention of unnecessary illness and premature death. We strive to achieve the national prevention objectives through surveillance, epidemiologic investigations, and laboratory research; by serving as national and international reference laboratories; by providing assistance, including grants, to State and local health departments; and by disseminating our findings through our other partners in academic institutions, medical care settings, and business and labor groups. During 1985, for example, our epidemiologists investigated over 680 outbreaks.

During the past 18 months, CDC has reexamined our Nation's health problems with the specific goal of identifying those areas in which there are significant opportunities to improve the health of people in this country. The reduction of infant mortality by deterring smoking during pregnancy, prevention of invasive cervical cancer, and prevention of injuries for older adults and minority groups are among the highest priorities we identified. This effort sharpened our focus on areas in which measurable improvements in morbidity, mortality, or quality of life can be achieved or anticipated using approaches that are feasible and appropriate for CDC. CDC's strategy for the future is to maintain our current expertise in prevention of a diverse array of problems while focusing on these new challenges to the extent possible.

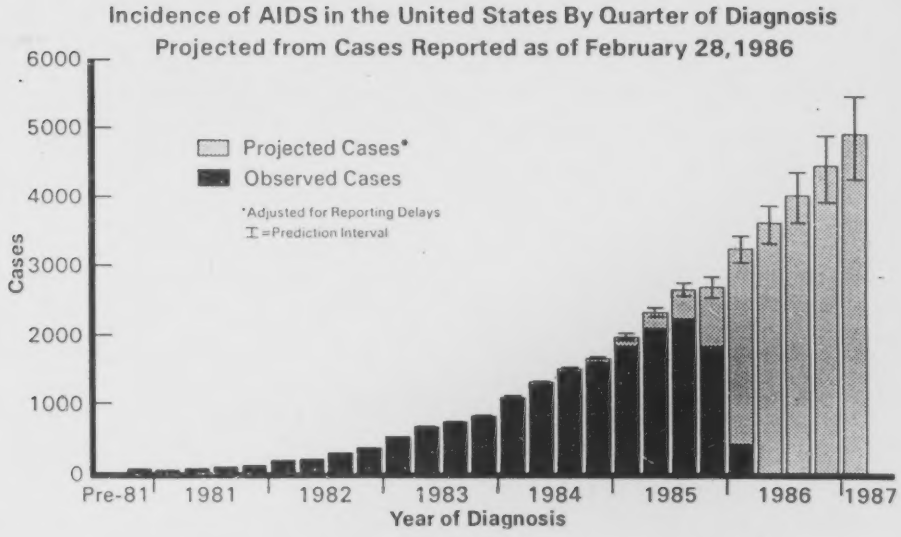
I would like to highlight a few of CDC's recent achievements and contributions to the application of public health practices at the community level, and illustrate the future directions of CDC's programs in five areas.

Acquired Immunodeficiency Syndrome (AIDS)

AIDS continues to be the nation's most visible health problem. As of February 28, 1986, there had been 17,869 cases and 9,463 deaths, about double the number of cases and deaths we reported to you last February. [chart]

Some progress has been made, however, toward controlling the spread of AIDS. Let me share with you a few accomplishments of the past year:

- To hasten the transfer of the HTLV-III serologic test for screening blood and plasma to protect the blood supply, CDC trained 145 laboratorians from 47 States in use of the HTLV-III serologic test; awarded cooperative agreements to 55 areas to establish alternate sites; and conducted 35 courses on pre- and post-test counseling for over 500 professionals. In cooperation with the Atlanta Red Cross, we demonstrated that the tests introduced for use by blood and plasma collection facilities were highly accurate in that setting. This study validated the use of the serologic testing procedure to reduce the risk to the nation's blood supply.



- o CDC laboratory scientists discovered how the AIDS virus attaches to and infects host cells. Understanding of this mechanism increases the chance of developing a vaccine and effective treatment methods.
- o CDC provided leadership in developing the overall Public Health Service plan for prevention and control of AIDS. We are also providing assistance to State health departments to support community-based information, education, and risk reduction activities.
- o We developed national guidelines and recommendations for serologic screening of blood and plasma; reducing sexual and drug abuse transmission; preventing perinatal transmission; preventing transmission of infection in the workplace; and for education and foster care of infected children.
- o The first International Conference on AIDS was held in Atlanta in April. Three thousand participants from 50 countries exchanged scientific information, and reviewed AIDS prevention and control strategies.

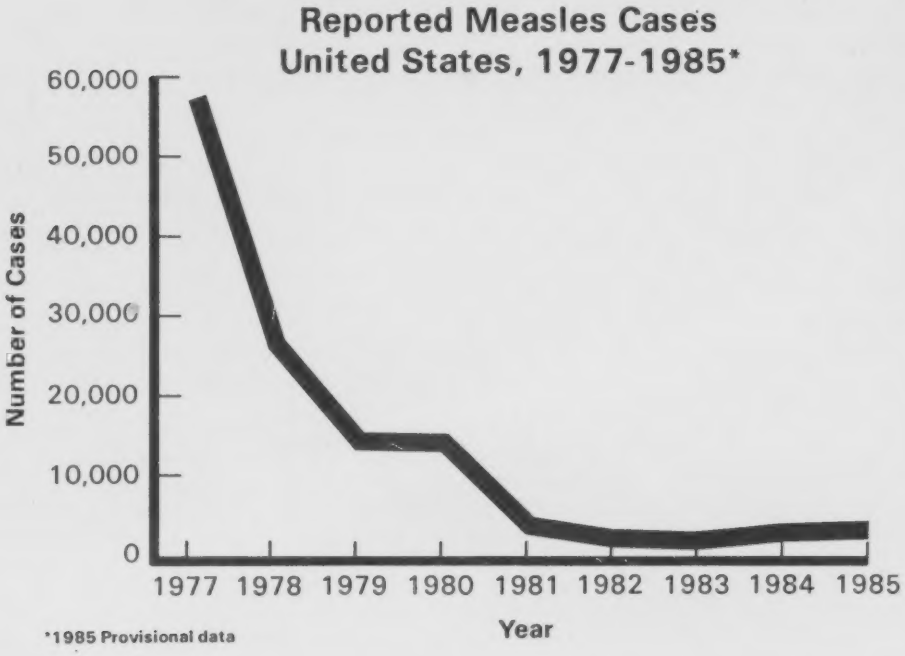
In the 1987 budget, funds for Public Health Service AIDS activities are combined under the Office of the Assistant Secretary for Health, but CDC will continue to be responsible for the operation of its portion of the AIDS activities. Within this budget, CDC plans to maintain support for AIDS surveillance systems, epidemiologic studies, laboratory work in virology and immunology, health education/risk reduction efforts, and development of more effective prevention and control strategies.

Infectious Disease Prevention

Apart from AIDS, infectious diseases are among the greatest causes of morbidity in the United States. Our best estimates indicate that 20-30% of all infections and 50% of deaths attributed to infections are preventable. Our programs include grants to States for immunization and sexually transmitted disease (STD) control activities, epidemiologic surveillance and

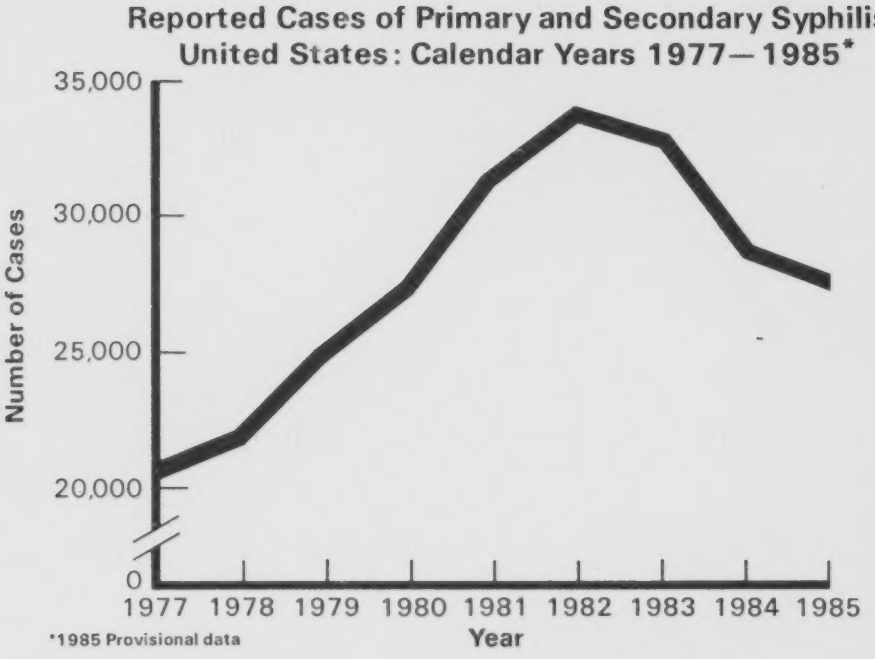
laboratory research designed to enhance the effective use of vaccines, and application of preventive techniques at the State and local level. By working closely with our public health partners in communities throughout this country, in 1985:

- o We maintained immunization coverage at record high levels of over 97% for measles, rubella, mumps, and polio, and diphtheria/pertussis/tetanus for children entering school. No cases of diphtheria or congenital rubella syndrome and only two cases of tetanus were reported in children under age 15. Record low numbers of cases of rubella and mumps were reported. Measles was below 3,000 cases for the 4th straight year despite importations and pockets of susceptibles that have prevented us from eliminating indigenous transmission altogether. [chart]



Partly as a result of U.S. accomplishments in controlling vaccine-preventable diseases among children, countries of the Western Hemisphere, including the U.S., declared the goal of polio eradication by 1990. A number of other countries have embraced the goal of measles elimination. These actions are increasingly important to our domestic epidemiological situation.

- o Support for State and local STD programs prevented an estimated 171,000 new gonorrhea infections and 5,500 syphilis infections. Primary/secondary syphilis morbidity decreased by 9.4%; the third consecutive year the rate has decreased. [chart]



- In collaboration with State health agencies and the Food and Drug Administration, CDC investigated two major epidemics: in Illinois, the largest outbreak of salmonellosis in U.S. history; and in California, an epidemic of listeriosis. The salmonella investigation revealed that the strain of salmonella was linked to two brands of milk from the same dairy plant which were not pasteurized properly. The listeriosis outbreak, which had over 140 cases and a 30% mortality rate, ended after manufacture of the cheese associated with the epidemic was suspended.

Much work remains to be done to control infectious diseases, however, for example:

- An estimated 3 to 4 million Americans suffer from chlamydia infections each year. Demonstration projects are underway to identify the key risk factors and evaluate our 1985 chlamydia control guidelines.
- To prevent bacterial meningitis among children and vaccine-preventable diseases such as pneumococcal pneumonia among high risk adults, CDC is working with State and local health departments and private practitioners to promote adoption of the national recommendations for adult immunizations and use of the Haemophilis influenzae b vaccine for children.

Chronic and Environmental Disease Prevention

Over 75% of the deaths in the United States each year are caused by chronic diseases, in children and adults. Heart disease and cancer combined contribute to over 3.3 million years of potential life lost annually. Unintentional injuries cause 3.4

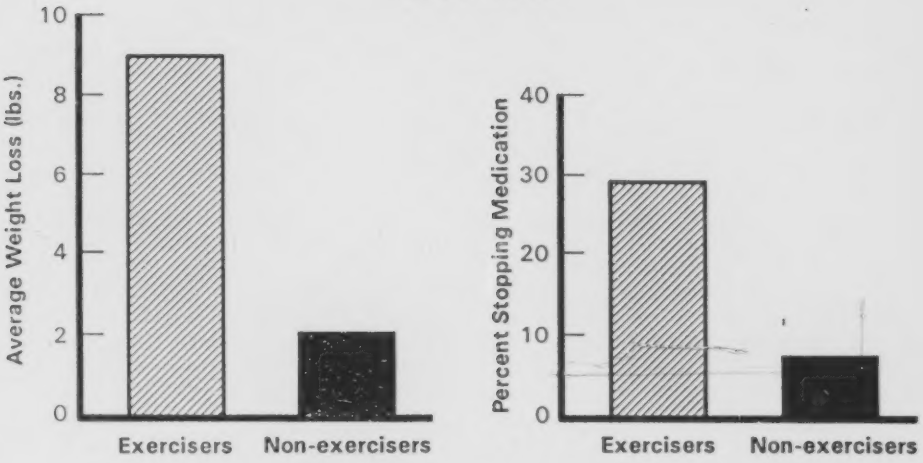
million years of potential life lost, more than any other health problem. Almost 4% of children under 17 years of age have chronic conditions that limit their activities. For persons 17 years of age and over, about 18% have limitations due to chronic diseases. These conditions are frequently the result of exposure to environmental hazards, genetic factors, and health and injury-related behaviors such as cigarette smoking, and lack of access and use of preventive measures such as high blood pressure control and pap smear testing. Chronic disease problems of this magnitude are no longer acceptable, because public health interventions are available or can be developed to prevent these conditions and their consequences.

CDC's program in chronic and environmental disease prevention is analogous to our approach to infectious disease prevention. We are working with State and local health and environmental agencies to help build their capacity in environmental health, chronic disease control, injury prevention and health promotion.

Recent achievements in these important areas are:

- Some 40 studies were begun to measure the health effects of exposures to toxic substances such as arsenic, polychlorinated biphenyls, lead, and dioxin. Our scientists are developing new methods for measuring body burdens of toxic substances and detecting the early stages of kidney or liver dysfunction.
- CDC assisted 7 States in investigating unusual clusters of injuries or fatalities. For example, an analysis of hospital admissions found that 9% of deaths in Alaska in 1983-84 resulted from transportation and recreational vehicle crashes. At least 20 of these deaths and 538 injuries were associated with 3-wheel all-terrain vehicles. Only 9% of riders wore helmets at the time of the incident. If people in communities would apply current interventions, we estimate that half of all injury-related deaths could be prevented.
- CDC's widely distributed School Health Education Evaluation findings, which we previewed in last year's hearings, allow us to state flatly that educating children about health is an effective health promotion tool. It enhances a child's working knowledge of health, and it clearly deters many children from adopting unhealthful practices such as smoking. Although over 625,000 children in 31 States participated this year in one CDC-developed curriculum, called "Growing Healthy," many children still receive little health education in schools. We are accelerating our work with States to increase the number of children benefitting from proven approaches.
- CDC's evaluation of a community exercise program on the Zuni Indian reservation demonstrated significant health benefits for diabetics who participated. Over two years, the average weight loss among participants was 9 pounds, compared with 2 pounds for nonparticipants. More significantly, 29% of the participants no longer require insulin or other drugs to control their blood sugar, as compared to 3% of the nonparticipants. [chart]

Effects of Community Health Promotion Program
Adult Diabetics, Zuni, New Mexico
1983-1985



- To determine the reasons for excess mortality from invasive cervical cancer and design interventions, CDC has a collaborative project with the Department of Health in Kentucky, the State with the second highest mortality rate from this disease. An estimated 6,800 women die from invasive cervical cancer each year. In theory, all of these deaths are preventable through early detection and treatment.

Our strategy in health promotion and chronic disease prevention is to work closely with the National Institutes of Health and State and local health departments to assist in translating research into public health approaches that can significantly reduce chronic diseases. We will continue to encourage reduction of health risks such as smoking, lack of exercise and poor nutrition through school health education and community-based health promotion programs.

Occupational Safety and Health

Each year about one out of every 10 workers in private industry suffers an occupational injury, about 4 out of every 100 workers is disabled, and about 7 out of every 100,000 workers are killed on the job. The National Institute for Occupational Safety and Health (NIOSH) has identified the ten leading causes of work-related diseases and injuries as: occupational lung diseases, musculoskeletal injuries, occupational cancers, traumatic injuries, cardiovascular diseases, reproductive disorders, neurotoxic disorders, hearing loss, dermatologic conditions, and psychologic disorders. [chart] In 1985, we convened a national conference of leaders in industry, labor unions, health professional organizations, and academia to develop strategies to address the first five of these problems.

Ten Leading Work-Related Diseases and Injuries

Occupational Lung Diseases	Reproductive Disorders
Musculoskeletal Injuries	Neurotoxic Disorders
Occupational Cancers	Noise-Induced Hearing Loss
Severe Occupational Traumatic Injuries	Dermatologic Conditions
Cardiovascular Diseases in Workers	Psychologic Disorders

In 1985, NIOSH had substantial achievements in a number of these areas:

- NIOSH has made progress in strengthening occupational disease surveillance systems. Through cooperative agreements, 17 States are developing their ability to monitor occupational illness and injuries and to improve the accuracy of reporting. In collaboration with the National Center for Health Statistics, NIOSH developed the capability to monitor cause-specific mortality for silicosis, asbestosis, coal workers' pneumoconiosis and mesothelioma.
- Over 550 health hazard evaluations were completed.
- In anticipation of increasing use of robotics in industry, NIOSH developed a safety system integrating engineering devices and comprehensive safety procedures to protect workers who maintain and program industrial robots and automated system installations.
- In a study of workers in a veterinary hospital in Georgia, we found that exposure to fenthion was causing neurologic effects. This pesticide was applied to dogs to control fleas. Although it is unknown how many of the estimated 30,000 veterinarians and 45,000 support workers were exposed to fenthion, NIOSH recommended that its use be discontinued.
- Since control of workplace hazards is most cost-effective when built into the initial design of machinery and worksites, NIOSH initiated a project with three schools of engineering to incorporate occupational safety and health into their curricula.

In 1987 CDC will continue its national program of research, surveillance, and worksite assessments of the hazards experienced by 104 million workers. Future directions include further development of national and State surveillance systems, evaluation and development of control technology, wide dissemination of safety recommendations and policy guidances, and research on the leading causes of work-related illnesses and injuries.

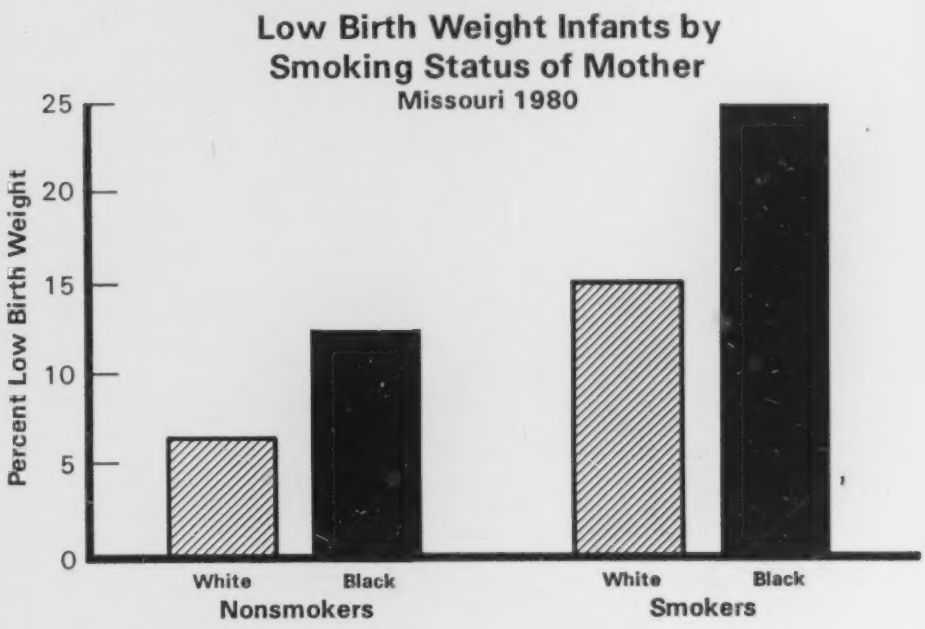
Infant Health

Assuring infants a healthy start in life and enhancing the health of their mothers are among the highest priorities in public

health. There has been extensive public concern about the disparities in rates of infant mortality and low birth weight between blacks and whites. Because the etiology of these problems is complex, there are no simple solutions. For example, even when factors such as education that are related to economic status are controlled, infants born to black women still have twice the risk of being low birth weight and dying during the first year of life. However, risk of low birth weight is strongly associated with preventable maternal behaviors during pregnancy, such as use of cigarettes and alcohol, and poor nutrition.

CDC has been working with other PHS agencies and State health departments to help to address excess infant mortality. For example:

- o In Missouri, we found that regardless of other risk factors, smoking doubles the risk of low birth weight. For very high risk groups, infants whose mothers also smoke have a 25% chance of being born with low birth weight. This is one of the key areas that States will be addressing through our initiative. [chart]



- o CDC epidemiologists assessed the years of potential life lost due to birth defects and found a 15.7% decrease from 1970-72 to 1980-82. Much of this decline may be attributed to improvements in the care of infants born with congenital anomalies, resulting in an increased survival rate. Since the rates of occurrence of most birth defects have remained stable over the last decade, the decline cannot be attributed to an overall decline in incidence. Cardiovascular system defects were the leading cause of premature mortality for infants with congenital anomalies.
- o Working with other PHS agencies (National Center for Health Statistics, National Institute of Child Health and Human Development, and Health Resources and Services

Administration) and State health departments, we completed the first national linkage of infant birth and death records since 1960. This analysis provides a powerful common data base for States to use in further assessing the contribution of low birth weight to infant mortality and targeting their control efforts more precisely.

In 1987, CDC is requesting $1.7 million to fund two components of the PHS Infant Mortality Initiative. Our main role is to improve the ability of States to monitor health-related behaviors associated with poor pregnancy outcomes by enhancing two existing surveillance systems. The Pregnancy Nutrition Surveillance System, which monitors women enrolled in the public prenatal programs, and the Behavioral Risk Factor Surveillance System, which monitors adult risk factors, will be expanded to enable States to assess pregnancy-related factors such as smoking and alcohol use, determine risk groups, and develop appropriate interventions. Through this initiative, we will also work with the Health Resources and Services Administration to provide epidemiologists to assist State Maternal and Child Health Programs in assessing problems associated with infant mortality.

Budget Request

In FY 1987, we are requesting $379.8 million, which includes $1.7 million for the CDC components of the PHS Infant Mortality Initiative. We are also requesting 4,015 FTE's, which includes 339 Reimbursable FTE's. This request includes $89 million for the Preventive Health and Health Services Block Grant. We have not requested funds in 1987 for the continued expansion of the vaccine stockpile. Since several issues are pending regarding liability legislation and the possibility that new manufacturers may enter the market, completion of the stockpile will be delayed until 1988 or beyond.

The revised FY 1986 budget request for CDC is $367.2 million, not including $50.3 million for AIDS, budgeted in the Office of the Assistant Secretary for Health on a comparable basis. This amount reflects a decrease of $20.3 million for the Gramm-Rudman-Hollings reduction and $34.1 million for proposed recissions. Taking into account the amounts that were sequestered, the proposed recissions include: $1.4 million for the Prevention Research and Demonstration Centers, $4.8 million for cooperative agreements for tuberculosis control; $4.8 million for cooperative agreements for State diabetes control; $1.0 million for the designer drug study; $11.8 million for AIDS alternative test sites and AIDS hotline; $8.4 million for occupational safety and health educational resource centers; and $1.9 million for equipment for the new virology building under construction.

I would be pleased to answer any questions from the Committee.

Biography of James O. Mason

POSITION : Director, Centers for Disease Control

BIRTHPLACE AND DATE : Salt Lake City, Utah, June 19, 1930

EDUCATION :
B.A. - 1954, University of Utah, Salt Lake City, Utah
M.D. - 1958, University of Utah, Salt Lake City, Utah
M.P.H. - 1963, Harvard School of Public Health, Boston, Massachusetts
Dr.P.H.- 1967, Harvard School of Public Health, Boston, Massachusetts
Internship, 1958-1959, Johns Hopkins Hospital, Baltimore, Md.
Residency, Internal Medicine, 1961-1962, Peter Bent Brigham Hospital, Harvard Medical Service, Boston, Massachusetts

EXPERIENCE :

1983-Present : Director, Centers for Disease Control

1983-Present : Administrator, Agency for Toxic Substances and Disease Registry

1985 : Acting Assistant Secretary for Health, Department of Health and Human Services

1979-1983 : Executive Director, Utah Department of Health

1978-1979 : Associate Professor and Chairman, Division of Community Medicine, Department of Family and Community Medicine, University of Utah College of Medicine

1976-1978 : Deputy Director of Health, Utah Division of Health

1970-1976 : Commissioner, Health Services Corporation, The Church of Jesus Christ of Latter-day Saints

1969-1970 : Deputy Director, Centers for Disease Control (CDC), DHEW, Atlanta, Georgia

1968-1969 : Chief, Infectious Diseases, Latter-day Saints Hospital and Assistant Professor, Department of Medicine and Preventive Medicine, University of Utah, College of Medicine

1964-1968 : Deputy Director, Bureau of Laboratories, Centers for Disease Control (CDC) DHEW, Atlanta, Georgia

1961 : Chief, Surveillance Section, Epidemiology Branch, Center for Disease Control (CDC), DHEW, Atlanta, Georgia,

1960 : Chief, Hepatitis Surveillance Unit, Epidemiology Branch, CDC, Atlanta, Georgia

1959 : Chief, Epidemic Intelligence Service, CDC, Atlanta, Georgia

TEACHING APPOINTMENTS : Clinical Professor, Department of Family and Community Medicine, University of Utah College of Medicine, May 1, 1979 to December, 1983

Clinical Professor, Department of Pathology, University of Utah College of Medicine, May, 1980 to December, 1983

Clinical Professor of Community Health, Emory University School of Medicine, October, 1984 to Present

ASSOCIATION MEMBERSHIP : Chairman, Utah Governor's Advisory Committee for Comprehensive Health Planning, 1975 to 1977

Chairman, Joint Residency Committee in Preventive Medicine and Public Health University of Utah College of Medicine, 1975 to 1980 Member, Utah Cancer Registry Research Advisory Committee, 1976 to 1983

Chairman of Board, Hospital Cooperative of Utah, July, 1977 to 1979 Chairman, Utah Health Planning and Resource Development Advisory Group Executive Committee 1977 to 1979

Member, Medical Association of Atlanta, 1985 to Present

Member, Institute of Medicine of the National Academy of Sciences, July, 1985 to Present

Member, twenty-two other committees or organizations

HONORS : Alpha Epsilon Delta, University of Utah 1954
Phi Kappa Phi, University of Utah, 1956
Alpha Omega Alpha, University of Utah, 1957
Roche Award, University of Utah, 1957
Wintrobe Award, University of Utah, 1958
Delta Omega, Harvard University, 1963
Sigma XI, CDC. Atlanta, 1964
Distinguished Alumni Award, University of Utah, 1973
Beatty Award, Utah Public Health Association 1979
Administrator of the Year Award, Brigham Young University, 1980

Special Award for Outstanding Public Service, American Society for Public Administration, 1984
Public Health Service Distinguished Service Medal, 1985

(Assistant Surgeon General, United States Public Health Service Commissioned Corps, effective November 29, 1983).

Questions Submitted by the Subcommittee

EFFECTS OF GRAMM-RUDMAN-HOLLINGS CUTS

Question. It is no secret that this Chairman is less than supportive of the so-called Gramm-Rudman-Hollings assault on the budget -- precisely for the reasons evidenced in your descriptions of the way in which sequestration affected CDC's budget.

I'd like to refer to two examples on page 60 of your document "Effect of Sequestration":

First, it says that, "Funds available to purchase chemotherapeutic agents for the treatment of patients with AIDS will be reduced by $297,000. The effect will be a reduction in the number of patients treated."

How many fewer people would be treated by chemotherapy as a result of this cut?

Answer. Congress provided us with $6.9 million, for fiscal years 1986 and 1987, to purchase chemotherapeutic agents for the treatment of AIDS patients not included in NIH clinical trials. Once the researchers determine that a drug is effective in the treatment of AIDS, but before Phase III Clinical Trials have been completed, it may be important to make the drug available to AIDS patients. Once safety and efficacy is clearly demonstrated, the drug could be made available under a Treatment Investigational New Drug (IND) application.

Since we do not have a drug approved for purchase at this time, it is impossible to determine cost of the treatment, and thus compute how many fewer patients could be treated as a result of the $297,000 decrease.

Question. How did you arrive at the decision to reduce the chemotherapy treatment program?

Answer. The resources provided for the AIDS chemotherapy treatment program met the definition for the program to be identified as a "program-project-activity" (PPA) under the Gramm-Rudman-Hollings Act, and therefore, the decrease was automatically required under the sequestering provisions of the Act.

Question. Are you planning to request either a supplemental or a reprogramming of funds so that chemotherapy treatment of AIDS victims be supported?

Answer. Since we do not know whether the remaining $6,603,000 will be sufficient to meet the need over 1986 and 1987,

we are not proposing either a supplemental or reprogramming of funds at this time.

U.S. IMMUNIZATION SURVEY

Question. Secondly, it says, "In addition, the Gramm-Rudman reductions in program operations will postpone the annual U.S. Immunization Survey. This survey provides information on national immunization levels which is essential for future planning and decision making."

How important to our knowledge about immunization program effectiveness and future planning is the annual U.S. Immunization Survey which will be postponed?

Answer. For immunization program planning purposes, the United States Immunization Survey (USIS) is not as essential as it used to be for determining the immunization status of school-age children, due to the development of more accurate assessment systems by the States. However, the USIS is still the only uniformly collected data about preschool children, and particularly about adult immunization status. When the USIS was first conducted, it was the sole measure of the estimated immunization level for the Nation. It is based on a national probability household survey that is conducted by the Bureau of the Census. Approximately 90 percent of the data produced by the USIS pertains to the assessment of the childhood immunization status and 10 percent to the assessment of adult immunization status.

Through this system immunization level data are collected on all children living in about 45,000 randomly selected households. A questionnaire is administered primarily by telephone to a responsible household member. Some of the information provided is simply that remembered by the respondent and is subject to considerable error. To lessen the chances of this error, the respondents are asked to find and review their child's immunization record before responding.

As the immunization program was developed, the need for more accurate assessment of childhood immunization levels by State was recognized. Therefore, a complementary system was proposed to and accepted by the grantees which becomes a part of their required grant supported activities. Now all State health departments collect immunization information for children when they enter the school system. All States have laws requiring all children to have basic immunization series, appropriate for age, to attend schools. This information is usually based on a verifiable immunization record that is presented by the parent or guardian to school officials, and is our most reliable indicator of immunization status. Information based on a subset of the total sample of USIS data (i.e., reference to an immunization record) is generally within about 10 percentage points of comparable data collected through the States' system for comparable ages. This subset is also believed to be a more accurate indicator of the immunizations status of the younger preschool children, but still subject to error.

Therefore, the school-aged childhood portion of the USIS is a less accurate indicator than the complementary data set collected by the States.

The two areas where the USIS provides important data not uniformly collected at the grantee level are the assessment of adult immunization levels and the assessment of immunization levels in the preschool population. With respect to the preschool population, some grantees collect several data sets on sub-groups of this population such as those attending licensed day care facilities, head start programs, EPSDT, etc. These data sets do provide indicators of the immunization status of the preschool population, but not on a uniform basis.

However, the USIS provides the only source of national data on adult immunization status. A complementing set of information on the net distribution of certain adult antigens remains available through CDC's Biologics Surveillance Program (BSP). The BSP is a system that monitors the net distribution of the national market of the major biologicals. While the information provided by this system is valuable, information on actual immunization status acquired through the USIS would allow more focused planning efforts in adult immunization.

Question. For how long will it be postponed?

Answer. For immunization program planning purposes, the United States Immunization Survey is not as essential as it used to be in determining the immunization status of school-age children, because of the development of more effective systems by the States. We think these new systems will be sufficient.

Question. Are you planning to request either a supplemental or reprogramming of funds so that this essential activity be supported?

Answer. At the present time, we have no plans to request either a supplemental or reprogramming of funds to conduct the USIS.

FULL-TIME EQUIVALENT STAFF

Question. Dr. Mason, at last year's budget hearing, the Committee appreciated your candor when you testified that you felt you needed a staffing level of 4,437 full-time equivalent positions (or FTEs) for FY 1986, and that this level could be supported with the amount requested by the President.

In the conference report accompanying our bill for FY 1986, we included language directing that "not less than 4,398 full-time equivalent positions be maintained."

Your budget documents, however, reflect an FTE level for FY 1986 at only 4,015 and, I note, the same level is requested for FY 1987.

Why is the FY 1986 FTE level so far below the amount you felt you needed to carry out CDC's activities as well as being far below the level directed in our Conference Report?

Answer. The reason for this reduction is the achievement of the President's objective to restrain Federal domestic employment.

Question. Let's try again. How many FTEs do you feel you need to conduct all your activities in FY 1987? How many did you originally ask of OMB?

Answer. Our 1987 budget submitted to OMB included 4,265 FTEs. I think that would be sufficient FTEs for the funds included in our 1987 request.

Question. At this point, I'd also like to ask you what was your original FY 1987 budget request that you submitted to the Secretary?

Answer. Our original request to the Secretary included 4,349 FTEs.

Question. To OMB?

Answer. Our request to OMB for 1987 was 4,265 FTEs.

CHILDHOOD IMMUNIZATION: DIPHTHERIA-TETANUS-PERTUSSIS

Question. Last year you described a series of factors leading to a shortage of the diptheria-tetanus-pertussis (DTP) vaccine and causing you to recommend postponement of the fourth and fifth doses for children to prevent an acute shortage. You testified last year that you expected to have inventories replenished by the end of 1985 so that you could begin recalling children who had missed their fourth and fifth doses.

Has this happened?

Answer. DTP vaccine supplies have become sufficient to recall all children who had either their fourth or fifth doses postponed.

Question. Please bring us up to date on the current status of the DTP vaccine supply and the recall of children for the completion of their prescribed dosages?

Answer. Virtually all children have been recalled by State and local health departments and private providers. Of course a small number may have been lost to followup.

Even though the current supply of DTP vaccine is adequate, Lederle has indicated that it is having problems in obtaining adequate insurance and will have to consider halting distribution of the vaccine. The liability issue remains the major threat to continuing supplies of DTP and other vaccines.

Question. As a followup, what is the status of our research efforts, specifically in the pertussis area, and what efforts are underway toward the development of new vaccines?

Answer. Currently CDC is sponsoring or collaborating on the following extramural projects:

- A randomized, controlled trial of two new acellular pertussis vaccines in Sweden. The trial, largely funded through a contract with NIH, began in February 1986, and results are expected by mid-1987.

- Two projects at laboratories in Virginia and Sweden to develop improved diagnostic tests for pertussis.

- A multi-state surveillance project in the U.S. to obtain better descriptive information on the epidemiology of pertussis in the U.S.

CHILDHOOD IMMUNIZATION - CUT IN FUNDING

Question. Like much of OMB's budget this year, the proposed request for the childhood immunization program provides the States with certain "options". For example, they can either purchase D-T-P (Diptheria-Tetanus-Pertussis) vaccines or fund State operations of the vaccine program.

How much more would it cost to fund both the continued Federal share of the DTP vaccine purchases and State administration of the vaccine program?

Answer. The FY 1987 request for the Immunization grant program is $47.7 million; this includes $32.9 million for MMR and OPV vaccines, and $14.8 million for DTP vaccines and/or State program operations. Based on the proportion of these costs estimated to be supported by Federal grants in FY 1986, a total of $58.8 million would be needed to maintain these same proportions in FY 1987. Of this total, $32.9 million would be for MMR and OPV vaccines (the same as the current request), $17.2 million would be for DTP vaccines, and $8.8 million would be for States program operations.

Question. What is the purpose of State operations to the overall effectiveness of the vaccine program?

Answer. CDC develops the national plan for the immunization program. The States are responsible for the implementation of the plan in their State. States have the responsibility to locate the unimmunized children and to assure they receive the proper immunizations at the appropriate time.

Question. What is involved in "State operations" in this effort?

Answer. State operations must: acquire, distribute, and administer vaccine; assure proper procedures are recommended and followed in storing and administering vaccines; ascertain vaccination coverage levels in certain population groups; develop and implement systems to detect adverse events following vaccination; conduct surveillance for vaccine-preventable diseases; investigate outbreaks of vaccine-preventable diseases and carry out emergency control programs; conduct public and professional education about the importance of vaccination; and carry out specific activities such as education of new mothers while in the hospital and recall of patients for future

vaccinations in order to assure complete vaccination at the recommended times.

Question. I presume the budget assumes the States will make up the difference.

Have you analyzed the ability of the States to make up the difference in both vaccine purchases and administration of the program?

Answer. We have not done an analysis of the ability of the States to make up the difference in both DTP vaccine purchases and program administration costs. However, we believe that the States, as partners with us in this effort, also recognize the importance of the immunization program and, where necessary, will seek to augment expenditures for State program administration costs and DTP vaccine purchases. The Federal government has only been providing funds for DTP vaccine purchases since 1985.

VACCINE STOCKPILE

Question. Dr. Mason, this year's budget does not request any funds to maintain an adequate stockpile of vaccines against childhood diseases, which has been funded at an annual level of $4 million in each of the past few years. What is the purpose of the stockpile?

Answer. The vaccine stockpile is designed to provide an assured supply of vaccine in the event of short-term (6 months or less) problems with vaccine manufacturing, lot testing, or strikes which have generated supply problems in the past. While the stockpile could be used in the event of manufacturer withdrawal from production due to liability insurance concerns, it was not designed to be the answer to this greater threat to vaccine supplies. Once the stockpile supply was exhausted, it could not be replenished if no manufacturers remained in the vaccine market, because of the lack of liability insurance.

Question. Am I correct that it is to guard against a shortage which could result in case of an epidemic or in the event of production stoppage at one of the new manufacturers of the vaccines?

Answer. Yes, you are correct.

Question. How close are we to the Department's previously stated goal of maintaining a 6-month stockpile of vaccines?

Answer. Funds have been appropriated through FY 1986 which will provide an aggregate 17-week supply of the major childhood vaccines in the stockpile, compared to the goal of a 6-month (26 week) supply. Individually, by vaccine, the following table displays the supplies currently in the stockpile and those expected to be accumulated by the end of FY 1986:

	Current Supply	Est. Supply at end of FY 1986
OPV:	18 weeks (68.1%)	20 weeks (78.3%)
DTP:	10 weeks (37.7%)	15 weeks (56.7%)
MMR:	12 weeks (47.3%)	14 weeks (53.8%)
Td:	16 weeks (61.4%)	18 weeks (69.8%)
DT:	10 weeks (40.0%)	15 weeks (59.0%)
IPV:	8 weeks (30.6%)	17 weeks (63.3%)

The ability of the contractor to meet its initial obligation to stockpile 37.7% of the 6-month target will depend upon production schedules and demands for vaccine. Current estimates are that the contractor will begin putting DTP vaccine in the stockpile in April 1986. Sufficient funds have been appropriated through 1986 to allow the eventual DTP stockpile to grow to 56.7% of the target amount.

Question. Isn't the stockpile a relatively inexpensive insurance policy against the threat of a sudden vaccine shortage?

Answer. A stockpile does provide an insurance for maintaining immunization levels during short-term interruptions. Having this backup reduces the risk that a backlog of unimmunized children would build-up in the case of a short-term interruption, and reduces the need for more costly and labor intensive recall programs for immunizations when normal vaccine distribution was resumed. However, the costs of continued increments to the stockpile are no longer inexpensive, given the recent rapid increase in vaccine prices, such as the growth in DTP vaccines from 11¢ a dose in 1982 to $4.42 a dose estimated for 1986.

Also, the stockpile is not a substitute for dealing with the issue of the availability of affordable liability insurance, which is a greater threat to vaccine supplies today. Once the stockpile supply was exhausted, it could not be replenished if no manufacturers remained in the vaccine market.

Question. When are you planning to resume expansion of the vaccine stockpile?

Answer. While bringing the stockpile up to an optimum 6-month supply remains a priority, several issues are now being considered in the area of vaccines that make it appropriate to delay further expansion of the stockpile for now. First, the Administration has transmitted legislation to the Congress to ban, unless negligence is proven, punitive and limit non-economic damage awards against vaccine manufacturers, to help ensure that these companies can obtain liability insurance. Second, new vaccines for DTP are being developed which are likely to replace the vaccines currently in use. Third, an additional manufacturer of OPV vaccine is expected to enter the market, and it is possible that a second company may be considering entering the MMR vaccine market. We expect that expansion of the stockpile could be resumed in the near future if these issues are resolved and funds become available.

Question. The budget documents indicate that it wouldn't be until 1988 or 1989 due to the need to resolve certain issues and

also because of concerns about "the efficiency of federal expenditures".

Are you more concerned about the "efficiency of Federal expenditures" (which are your words on page 34 of the justification) than you are about protecting our nation's children against childhood diseases?

Answer. The efficiency of Federal expenditures is important, but I am dedicated to protecting the Nation's children against childhood diseases.

PROMISING NEW VACCINES

Question. Your testimony indicates that CDC is "working with" various State and Private Health Professionals to promote the use of the haemophilus influenza "B" vaccine for children.

How effective is this new vaccine in preventing bacterial meningitis?

Answer. Haemophilus influenzae type B polysaccharide vaccine (HBPV) efficacy varies greatly with the age of the child at the time the vaccine is administered. This vaccine can be expected to reduce the risk of Hib meningitis in children vaccinated at 24 months of age or older by approximately 90 percent. The expected degree of protection in children vaccinated between 18 and 23 months of age is uncertain but has been estimated to be on the order of 50-75 percent. The current vaccine affords no protection in children immunized below 18 months of age. Based on these data, the optimal age at vaccination is 24 months of age. Information regarding revaccination of those vaccinated before 24 months of age is being formulated. It is expected that a new HBPV given in combination with DTP vaccine at 2-4 months of age will be effective in infants. This vaccine is anticipated to be available for use within 2 years.

Question. How are you promoting the use of this vaccine without any allowance for it in your budget?

Answer. The Centers for Disease Control, as part of its effort to make vaccines available at the lowest possible cost, has negotiated a consolidated contract that will permit States to use Federal, State, and local funds to buy HBPV at a cost considerably lower than the current commercial cost. CDC is also assisting the States by developing and distributing the ACIP-recommended "Important Information Form" to better alert consumers to the importance of the HBPV vaccine. We are also collecting additional information from the States about their current capabilities and intent with respect to the provision of HBPV.

Question. How much would it cost to include this vaccine as part of the federal childhood immunization grant program on an annual basis?

Answer. Traditionally about half of all vaccines administered are provided in the private sector and the other half must be delivered by the public sector to obtain adequate

immunization levels. If we assume this same pattern holds true for HBPV, it is estimated that approximately $8,000,000 would be required to fund the public sector's cost in fiscal year 1987. This assumes that the public sector cost of the vaccine, which is less than half the private sector cost, will increase 25 percent between 1986 and 1987, the same assumption which has been made for the increase in MMR, OPV, and DTP vaccines. Without limitation on vaccine liability, we anticipate that the cost of vaccine will increase a minimum of 25 percent each year.

Question. What other effective vaccine exist to combat certain serious diseases but are not now included under the Federal Immunization Grant Program?

Answer. While there are no other vaccines for children not now covered by Federal grants, it is possible that the varicella (chickenpox) vaccine may soon be licensed for use in all children.

Question. How much would it cost to include them in the Federal program?

Answer. Assuming a price tag of $10 per dose of varicella vaccine, and one dose per child, and assuming the States made no financial contribution to providing the vaccine then the cost of a Federally sponsored program would be $37 million to cover all children. To cover the traditional public-sector share of one-half of the target population, the cost would be $18.5 million.

AIDS - FUNDING REDUCTIONS

Question. The FY 1986 appropriation was $65 million. The FY 1987 budget request is $45.8 million for AIDS activities of CDC. Dr. Mason, your FY 1987 Budget request proposes a 30 percent cut in AIDS funding from the level appropriated in FY 1986. How do you justify this reduction?

Answer. Funds appropriated in FY 1986 that have been deleted from the FY 1987 request include $1.9 million for a 24 hour information hotline and $9.9 million for alternate site testing. The decision to propose not to implement an expanded hotline was based on a judgment that the current PHS hotline service, which operates five days a week and provides live operator response to callers eight hours a day, supplemented by various locally operated AIDS hotlines around the country, is adequate to meet the informational needs of the public. Also, locally-supported hotlines are in a better position to refer those in need to local service and counseling capacities. A survey by the Conference of Mayors in 1985 of 55 cities determined that two-thirds operated AIDS hotlines.

Congress provided two year funding of $6.9 million in 1986 for the purchase of chemotherapeutic agents for the treatment of AIDS patients not included in the NIH Clinical Trials prior to the agent being licensed by FDA. Additional funds are not needed in 1987 because of the two year provision.

The decision to propose not to continue funding of the alternate site testing program for HTLV-III/LAV antibody was based on the original intent of the program announcement for this

funding, which indicated the availability of "one time, start up resources." As the funds awarded by CDC are gradually expended, we expect that most areas will be able to identify the resources needed to keep their alternate testing sites functioning and capable of meeting the local demand for service.

Question. Which of the activities provided for in the original FY 1986 Appropriation would not be continued?

Answer. The current AIDS hotline would not be expanded to operate 24 hours a day and seven days a week, and continuation funds for the alternate site testing program would not be provided to the States.

AIDS ALTERNATE TEST SITES

Question. What is the purpose of the alternate test sites for blood screening?

Answer. On March 2, 1985, an enzyme-linked immunosorbent assay (ELISA) test to detect antibodies to human T-lymphotrophic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV), the virus causing acquired immunodeficiency syndrome (AIDS), was licensed by the Food and Drug Administration (FDA). FDA licensed the ELISA test for the purpose of screening units of blood for antibody to HTLV-III/LAV and for general screening of high risk populations. To protect the Nation's blood supply, it was recognized that alternate testing sites should be available so that individuals in recognized AIDS risk groups would not donate blood at blood banks and plasma centers simply to receive free HTLV-III/LAV antibody testing. These alternate sites were also designed to assure that individuals received appropriate pretest counseling, posttest counseling, and that persons with positive tests are referred for medical evaluation. In the year following licensure of the test, approximately .25% of persons donating blood have been positive compared with 17.3% of persons attending alternate testing sites.

Question. What were your plans for the $9.934 million which was targeted for the alternative test sites program and rescinded from the FY 1986 budget?

Answer. Funds in FY 1985 for alternate testing sites were made available to States and certain large cities having many cases of acquired immunodeficiency syndrome (AIDS) on the understanding that these were "one-time, start-up" resources. As a result, the Administration did not include funds for the Federal Government's continued support of alternate testing sites when it submitted a FY 1986 Budget Amendment for AIDS activities in September, 1985. Nevertheless, Congress appropriated $10.4 million for an AIDS alternate site testing program in FY 1986. Because continued Federal support for this program was never anticipated, a rescission was requested.

Question. Are the State and local governments prepared to continue with alternate test sites without CDC's support, or has the demand for the service the alternative test sites provided decreased?

Answer. Funds in FY 1985 for alternate test sites were made available to States and certain large cites having many AIDS cases on the understanding that these were "one-time, start-up" resources. Initial project periods of 90 days were extended an additional 90 days for all recipient areas. Recipients which had unexpended funding balances at the end of that 180 day period applied for and were granted an additional extension of approximately six months. Funds were provided to State and local governments to provide maximum opportunity for the States to identify means of supporting the continuation of alternate testing sites. All evidence suggests that the demand for the services they provide has steadily increased nationwide. The number of alternate testing sites has risen to meet this demand and nearly 1,000 are currently in operation even though funds from the FY 1985 Federal project awards have been used up by most grantees. THis suggests that States are now supporting their alternate testing sites without the $9 million proposed for rescission.

CENTRALIZING AIDS EFFORTS

Question. How will centralizing AIDS funding under the Assistant Secretary for Health affect AIDS-related activities in CDC?

Answer. We do not expect any adverse effects on CDC's AIDS related activities as a result of centralizing AIDS funding under the Assistant Secretary for Health. We are to get the same basic amount of money and as rapidly under this proposal as we would have if it had come directly to us. It does provide the Assistant Secretary with some flexibility to meet emergencies, and redirect resources as scientific breakthroughs occur and as new, urgent opportunities are identified.

Question. What will happen to the priorities already established and in some cases begun in FY 1986, such as the 24-hour information hotline and the alternate blood testing sites, assuming Congress rejects the proposed rescission?

Answer. If the proposed rescissions are rejected, we would move as quickly as possible to implement both programs in FY 1986 as directed by Congress.

SEXUALLY TRANSMITTED DISEASES

Question. CDC's sexually transmitted disease prevention efforts have been fairly successful in reducing the incidence of venereal diseases. We understand, however, that you have information that as a result of the Gramm-Rudman-Hollings cuts, you anticipate that fewer cases of gonorrhea will actually be prevented as the incidence of this disease increases.

Am I correct? Does your information show that you can equate actual funding cuts with an increasing incidence of sexually transmitted diseases?

Answer. Reductions of Federal grant funds to the States for disease intervention activities from 1951-1955 resulted in a 3-fold increase in infectious syphilis by 1961. Similarly, the

steady decrease in funding available for infectious syphilis intervention activities from 1977-1982 was accompanied by a doubling of the reported incidence in the same period. The reason for this cause-effect relationship is clear; as disease intervention resources are reduced, the reservoir of undetected or unidentified infection is permitted to increase. The larger the number of undetected, yet infectious cases there are in the community, the more likely it is for high risk individuals to become exposed to the disease. We anticipate that this relationship would hold true for gonorrhea as well.

Question. The Committee has received information indicating that between 15 and 30 percent of sexually transmitted disease control funds and as much as 45 percent of staff time has been devoted to AIDS efforts.

Is this accurate?

Answer. In Fiscal Year 1985, an estimated $6.5 million (12.3 percent) in STD project grant and direct operations funds and approximately 32 full-time equivalent (FTE) positions (7.3 percent) were used to support various AIDS-related activities. However, the commitment was not equalized throughout the period, and expenditures at the end of the fiscal year were much higher - in the range of 30 percent. In FY 1986, it is estimated that about $6.5 million in STD resources and 45 FTE's will be devoted to the AIDS efforts.

Question. What has been the effect on the control and prevention of the other sexually transmitted diseases as a result of the "diversion" of sexually transmitted disease funds to AIDS efforts?

Answer. In STD project areas, AIDS-related activities involve staff and resources for various AIDS organizational, educational, and epidemiological activities. However, expanding pre and posttest counseling, HTLV-III/LAV antibody testing, other health education/risk reduction activity and sex partner referral to STD clinics, will have a significant impact upon STD resources.

It is possible, for example, that STD field staff will be asked to assume some increased responsibilities in AIDS intervention activities because of their training and experience in interviewing/counseling and sex partner referral. On the other hand, the STD program has reaped benefits from its involvement in AIDS activities, including closer liaison with gays and prostitutes who are important STD program constituents. At this point it is difficult to predict the overall effect of the diversion of STD resources to AIDS-related activities, but the early reading is positive concerning the more traditional STD prevention and control activities. For example, in 1985 and thus far in 1986, the three States with the highest incidence of AIDS, California, New York and Florida, have shown reduced levels of reported gonorrhea among gay males despite modest increases in overall morbidity.

Question. Is our funding level for CDC AIDS efforts so inadequate that we must divert funds appropriated for other sexually transmitted diseases?

Answer. The diversion of STD funds to support HTLV-III/LAV related activities is more a matter of necessary expediency than anything else in order to take advantage of the availability of trained people. The AIDS epidemic is the number one public health problem in the country. As such, action to develop and implement counseling, testing, and control strategies must not be delayed. Since the majority of patients with AIDS or HTLV-III/LAV infection are also at high risk for STD, many areas decided to give STD program personnel the operational responsibility for the AIDS effort because they could get the job done more quickly and effectively. Disease intervention specialists in STD have the required training and experience in interviewing/counseling and sex partner referral. STD program managers are experienced in managing not only STD programs, but also in developing, implementing, and evaluating innovative operational methodologies. The traits necessary for effective STD prevention and control programs are also necessary for effective AIDS activities. Therefore, many States and localities saw it logical to have their STD personnel assume additional responsibilities in AIDS at virtually every functional level.

PREVENTIVE HEALTH AND HEALTH SERVICES BLOCK GRANT

Question. The Gramm-Rudman-Hollings sequestration order has resulted in a $3.9 million reduction of funds for the Preventive Health and Health Services Block Grant which the States use for such authorized purposes as emergency medical services, rodent control, fluoridation, rape crisis services, and various other comprehensive public health activities. This reduction results in a level for the block grant in FY 1986 that is below the FY 1985 appropriation.

Which of the program activities covered by this block grant will suffer the most under this reduction of funds in the current fiscal year?

Answer. There is no way to determine which programs will suffer as a result of the reduction as each State makes its own decision on how to expend its block grant funds. Only significant changes to a State's plan for use of funds needs to be published in that State and a copy furnished to the Government. No such notices have been received.

Question. The 1984 Health Amendments direct the Secretary to develop information and data collection procedures relating to the way in which States use their block grant funds.

What is the status of implementation of this requirement? When will States be able to share data and information on exactly which services they are able to support and which are unfunded?

Answer. In response to the new data directive, CDC initiated and conducted a meeting with several health associations. The associations represented by their Executive Director and a local or State health officer were: American Public Health Association, National Association of County Health Officials, United States Conference of Local Health Officers, and the Association of State and Territorial Health Officials.

The consensus of the group was not to initiate a new reporting system, but to build on the ongoing system operated by the Association of State and Territorial Health Officials. The system is partially supported by CDC for analysis and publication of the data. The four associations have agreed to work together in the development of model criteria in the form of new/revised input questions with an emphasis on uniform information that can be shared by the States. The results of these efforts will be submitted to CDC for review.

It is anticipated that these new/revised questions will be used to collect information on services supported with block grant funds in FY 1986. However, considerable information on these services is currently available as a result of voluntary reporting by the States to the Association of State and Territorial Health Officials Foundation. The most recent version of these data, published in January 1986, is titled, "Special Report: State Health Agency Use of the Maternal and Child Health Services and Preventive Health and Health Services Block Grants, 1981-1983."

TUBERCULOSIS GRANTS

Question. Again, you are proposing the elimination of the tuberculosis grant program. Although the incidence of tuberculosis in our country has continually declined each year, we are recently experiencing a reduction in the rate of decline. The rate declined by 6.7% in 1984 but only by 2.5% in 1985.

How concerned should we be about a possible resurgence in the incidence of this disease?

Answer. We are very concerned about the leveling off of the downward trend in the incidence of tuberculosis in the United States and we are looking closely at the problem. The provisional total of 21,801 tuberculosis cases reported for 1985 (case rate of 9.13 per 100,000) is a provisional decrease of only 2.0 percent from the final tuberculosis case total for 1984. During the previous three years (1982, 1983, and 1984), tuberculosis morbidity declined an average of 6.7 percent each year.

Although the reasons for the relatively small decline in 1985 cases are not fully known, we have evidence that human T-lymphotrophic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV) infection of persons infected with the tubercle bacillus has caused a tuberculosis increase in some areas. CDC epidemiologists and tuberculosis program personnel are working closely with health departments in Florida and New York City on studies to better define and understand the tuberculosis/AIDS/HTLV-III problem and to design the most effective and efficient control strategies. CDC continues to provide technical assistance and training to State and local health departments and to develop national tuberculosis control policies and recommendations. Progress has been made in the implementation of newly recommended, more effective, and less costly short-course therapy regimens. Tuberculosis funds have been used for directly observed therapy for noncompliant tuberculosis patients in order to reduce the transmission of tuberculosis in high incidence areas. We are urging health departments and other health care providers to

conduct tuberculosis screening programs for persons at high risk (e.g. contacts of cases, immigrants, health care workers, residents and staff of prisons, nursing homes and other institutions, etc.) and to intensify the use of preventive therapy among those found to be infected. We will continue to assess the problem through collection of morbidity and program management data.

Question. What evidence do you have that States would be able to use Preventive Health Block Grant funds to replace the tuberculosis grants, particularly in light of reductions in the block grant?

Answer. We believe many States will allocate Preventive Health Block Grant or other funds for tuberculosis control activities. Most State and local health departments, particularly those with significant tuberculosis problems, recognize the need to keep the disease in check. Experience with the Tuberculosis Cooperative Agreements since 1982 has demonstrated the effectiveness of intensified prevention and control activities in many high incidence areas. Some areas have reported substantial cost savings because noncompliant patients who previously needed to be hospitalized for treatment of tuberculosis can now be treated successfully on an outpatient basis. Based on the experiences in using these funds, the States are now in an excellent position to evaluate funded activities and determine where they rank among the other priorities of the States. We are convinced that many States will want to continue applying the outreach technologies developed through this grant where they have proven to be exceedingly cost effective versus the alternatives of continued community spread or costly long-term hospitalization of noncompliant patients.

In general, we believe that the block grant approach is the most effective way for the Federal Government to assist States to address public health and other problems. This approach is consistent with the Administration's commitment to balance the budget and keep inflation in check. Block grants permit States to establish their own priorities and to direct funds to those problems which they perceive to be the most urgent.

In addition, the 1987 budget request for the Refugee Preventive Health Program, for the Office of Refugee Resettlement, is $10.3 million, an increase of $2.3 million over the 1986 level. Funds from this program are available to State and local health agencies for TB control, therapy, and follow-up for those refugees identified as being TB infected and eligible for preventive treatment.

Question. What can you tell us about the incidence of tuberculosis among homeless Americans? What is the likelihood that, as the numbers of homeless persons increase, the incidence of tuberculosis will also increase? What are the chances that the tuberculosis among the homeless will spread to the rest of the population?

Answer. The homeless are from lower socioeconomic groups where tuberculosis case rates are generally higher. Furthermore, stress, alcoholism, drug addiction, and low body weight are more

common among the homeless and these conditions have been reported to increase the risk of tuberculosis. We do not know the precise incidence of tuberculosis among the homeless in the United States, because most State and local health departments do not collect or report to CDC information on homeless tuberculosis patients. In 1983, the tuberculosis case rate among homeless persons in Boston was 50/100,000 as compared to 19/100,000 for the city as a whole and 4.8/100,000 for the State. During 1984 and 1985, there was an outbreak of tuberculosis among the homeless in Boston. The case rate among the homeless increased to 317/100,000. This outbreak was associated with three large shelters and appears now to have been contained. Last year, Portland, Oregon reported 22 confirmed cases of tuberculosis among a generally transient and homeless population.

If the number of homeless persons increases, it is possible that there would be an increase in the incidence of tuberculosis among this group. We will continue to work with State and local health departments to establish effective screening and prevention programs in these groups.

Tuberculosis is an airborne disease and transmission of infection is related to sharing airspace with an infectious patient, usually for a prolonged period of time. There is little risk that tuberculosis among the homeless will spread to persons who have only brief and casual exposure. However, homeless persons with infectious tuberculosis are at risk of spreading infection to others with whom they have close and prolonged contact, e.g., other homeless persons, workers in shelters for the homeless, and health care workers who care for homeless persons. For this reason, tuberculosis screening and prevention programs for the homeless and those who care for them are encouraged.

Question. What resources do States and cities have to deal with the problem of tuberculosis among the homeless population?

Answer. State and local governments have traditionally assumed the responsibility for most of the costs of prevention and control of tuberculosis in the community. Normally, services to homeless tuberculosis patients are provided in health department and other public clinics. When hospitalization is necessary, homeless patients are often eligible for Medicaid or Medicare coverage.

STATE DIABETES CONTROL PROGRAM

Question. The State Diabetes Control Program, funded at $5 million within chronic disease activities, would again be eliminated under your budget. Congress, as you know, has repeatedly rejected this proposal in past years.

Do you believe that there are no long-term health-related and economic benefits to this program which are worthy of Federal support?

Answer. We agree that there have been long-term health-related and economic benefits to the State diabetes control demonstration projects. However, because of the need to constrain

Federal spending, we believe it is now appropriate for these demonstration projects to be continued by the States or other third-party payors who have also benefitted financially from their success. The goals of this demonstration effort were to reduce complications of diabetes by improving the health care delivery system and to achieve State diabetes control self-sufficiency. Many of these projects were shown to be cost-effective. For example, we have demonstrated that targeted outpatient education can lead to reductions in hospitalizations and that prepregnancy counseling can reduce the five-fold risk of congenital anomalies among offspring of diabetic women. Based on estimates derived from clinical trials and epidemiologic studies, we estimate that complication-specific interventions could save $21 million per year for neonatal intensive care costs for infants with congenital malformations born to women with diabetes, $87.8 million per year due to diabetes-related blindness, and $50.4 million per year for diabetes-related amputations in the Medicare population alone.

Question. On what evidence is the elimination of this program based?

Answer. This program was designed as a 5-year demonstration program. During its 8 years of existence, the program has proven successful in developing methods to reduce complications of diabetes and in developing State self-sufficiency. In FY 1984, four to five States made in kind contributions of approximately $3.5 million to support the State diabetes control programs while 15 other States contributed a total of $1 million. Other States have been successful in obtaining third-party reimbursement for diabetes patient education programs.

Question. Again, this year your budget request eliminates all funds for training occupational safety and health professionals.

What evidence do you have to support the idea that State governments and the private sector will be able to, and will in fact, support such training at regional Educational Resource Centers (ERCs) should the Congress agree to your proposal to eliminate such funding?

Answer. It is the Administration's belief that continuation support for the ERCs should come from those non-Federal sources who benefit directly from the employment of those occupational safety and health professionals who received academic or continuing education training from the ERCs.

The ERCs currently receive approximately 25 percent of their funding from sources other than the NIOSH federal training grant. Two California ERCs have supplementary State funding. The Washington ERC receives some funding from the Statewide workers compensation funding pool. Some of the State-funded universities with ERCs have increased faculty support. The ERCs have begun discussions with potential non-Federal funding groups. The American Industrial Hygiene Foundation has developed a trust fund to provide some scholarships and grants to individual students. These funds include donations from corporations and individual donations from AIHA members. More recently, the American

Occupational Medical Association is exploring the feasibility of private funding sources for occupational-medical residency programs. The universities will have to explore expansion of these alternate funding sources in order to support the ERC programs.

Question. What monitoring mechanisms are planned to be sure that the training of effective occupational safety and health professionals, formerly performed by the National Institute for Occupational Safety and Health, will continue with funding only by State governments and industry?

Answer. NIOSH will conduct periodic surveys among employers of occupational safety and health professionals and among the students and faculty of training programs.

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
VIDEO DISPLAY TERMINALS

Question. We understand that last year a National Institute for Occupational Safety and Health (NIOSH) study of the effect on pregnancy of video display terminal (VDT) operation was planned but then cancelled. Why?

Answer. This study was prompted by reports of adverse reproductive outcomes in some women VDT operators. We are aware of reports appearing in the news media of 12 clusters of adverse pregnancy outcomes among VDT users. These clusters ranged in size from 3 to 24 women. In some cases, the numbers exceeded what would have been expected in the general population. Although it is possible such clusters may reflect a relationship with VDT use, it seems likely that they represent a chance occurrence that is statistically predictable. The alleged cause was radiation from the VDTs. We have no scientific evidence that VDTs cause adverse reproductive outcomes. Moreover, NIOSH has conducted numerous radiation surveys of VDTs and has found no evidence of a radiation problem. Still, workers' concerns persist. Therefore, we proposed a large epidemiologic study of this issue.

Due to the proposed data collection needs, the OMB Office of Information and Regulatory Affairs reviewed our research protocol on the possible reproductive effects of VDTs under the provisions of the Paperwork Reduction Act. On December 13, 1985, OMB rejected the research protocol and cited four reasons:

1. The sample size is barely adequate to investigate the incidence of miscarriages and is insufficient to test the hypothesis of other increased pregnancy reactions.
2. The sample frame is incorrectly defined.
3. The major variables that will be used in the analysis, including morbidity, exposure, and birth defects, are poorly defined.
4. A large number of irrelevant questions with no practical utility are included.

We have revised the protocol pursuant to the comments that we agree with, and the revised protocol is being reviewed by our peer reviewers, the company, and the involved unions. We will

resubmit (Spring 1986) the study to OMB for reconsideration. We believe the resubmission will answer their concerns satisfactorily.

Question. Isn't it true that the United States is one of only a few remaining developed nations in the world not to have an occupational or public exposure standard to protect VDT workers?

Answer. Our response is based on the assumption that it refers to radiation exposure standards and not other health issues of VDTs such as ergonomic concerns. There are many types of radiation emissions from VDTs, such as x-ray, ionizing UV, and microwaves. In May of 1984, NIOSH conducted a review of the standards/recommendations from other countries concerning radiation exposure and found the following:

1. Canada - No radiation standards specific to VDTs, however, standards for other types of electromagnetic equipment do apply as appropriate.

2. Germany - No specific radiation standards. However, standards for other electromagnetic equipment do apply.

3. Sweden - None found.

4. Holland - None found.

5. Great Britain - None found.

6. Austria - Adopted German standards (standards for other electromagnetic equipment apply).

7. Australia - None found.

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

Question. How many standards has the Department of Labor promulgated to protect workers from particular occupational hazards as a result of NIOSH research findings since the establishment of NIOSH in 1972?

Answer. NIOSH has routinely provided research findings to support DOL regulatory action since NIOSH was established. We have submitted findings in the form of criteria documents, or regulatory responses on all of the health standards the Occupational Safety and Health Agency (OSHA) has promulgated on particular occupational hazards. However, NIOSH research findings are only one portion of the information that OSHA considers in deciding to promulgate a standard. OSHA considers research findings from all sources of occupational safety and health research. The DOL then considers the research findings available along with economic factors related to possible regulatory actions and considers public policy issues in determining whether to promulgate regulations and in determining the nature of those regulations.

Question. How many recommendations by NIOSH for standards did not result in standards being promulgated by the Department of Labor?

Answer. We have transmitted 118 criteria documents to the Department of Labor (DOL). The DOL has exactly incorporated the recommendations from 7 of these criteria documents into standards. However, generally, NIOSH recommendations for standards, which include consideration of NIOSH research and research conducted elsewhere, do not directly result and are not exactly incorporated into standards being promulgated by the DOL. As previously discussed, our recommendations are only one portion of the information the DOL considers in deciding to promulgate a standard.

Question. For what reasons?

Answer. We base our recommendations for standards strictly on the scientific evidence available indicating an occupational health or safety hazard. This was deliberately conceived by the authors of the Occupational Safety and Health Act (P.L. 91-596) in establishing the National Institute for Occupational Safety and Health (NIOSH) as a research agency in the Department of Health and Human services and entirely separate from the occupational safety and health regulatory agencies in the Department of Labor (DOL). This way, the authors helped guarantee that the integrity of the science conducted in this field would be insulated from concerns based on the economic and other public policy issues involved in regulating the workplace.

In addition to considering scientific findings, the Department of Labor has to consider economic factors related to possible regulatory actions and consider public policy issues in determining whether to promulgate regulations and in determining the nature of those regulations.

Question. Can you cite some examples of recommendations for standards requested by the Labor Department?

Answer. NIOSH routinely provides written testimony to MSHA and OSHA in response to notices of proposed rulemaking and provides testimony at rulemaking hearings. Some specific examples of instances in which OSHA directly requested our assistance, other than through the formal rulemaking procedures, are as follows:

1. In 1972, OSHA requested information on nine substances alleged to be carcinogens.

2. In 1974, OSHA asked whether a benzene standard should consider carcinogenicity and, if so, what level would provide adequate protection.

3. In 1975, OSHA requested us to re-evaluate the information available on the adverse health effects of occupational exposure to beryllium.

4. In 1977, OSHA requested formal review of the "Occupational Carcinogen Policy."

5. In 1985, MSHA requested us to conduct (1) a critical evaluation of the existing epidemiologic literature on radon daughters, and (2) a quantitative risk assessment on radon daughters.

Question. What efforts have NIOSH and the Department of Labor expended to try to reduce the number of recommendations which do not result in standards?

Answer. The Occupational Safety and Health Act (Section 22) charges NIOSH with providing recommendations for the development of new and improved occupational safety and health standards. Some of this activity is initiated in response to planned and ongoing Department of Labor (DOL) regulatory activity or direct requests for assistance from the DOL. However, much of our activity in this area proceeds independently of DOL activity. We develop recommendations in response to developments in scientific information produced by NIOSH and other researchers in occupational safety and health. As a result, our recommendations represent NIOSH's separate evaluation of regulatory needs in occupational safety and health. To ensure that NIOSH and the DOL are informed of each others' activities, representatives of the DOL and NIOSH hold monthly meetings.

FLUORIDATION

Question. Since 1982, Federal funding for new fluoridation projects is included under the Preventive Health Services Block Grant rather than through a separate grant program.

What changes have occurred, if any, in the States' abilities to fluoridate public drinking water supplies as a result of the block granting of this program from 1983-1986?

Answer. The latest Association of State and Territorial Health Officers' (ASTHO) report on the amount of Preventive Health and Health Services Block Grant funds spent by State Health Agencies for fluoridation activities only includes data on expenditures through FY 1983. More recent data is not yet available.

Question. Is there enough funding for such efforts, in your opinion?

Answer. One of the purposes of the Preventive Health and Health Services Block Grants was to provide funds to the States for the continuation of programs like fluoridation if the need was evident.

Approximately 61.4 percent of the U.S. population on public water systems receive fluoridated water. This leaves almost 39 percent of the population on public water systems without the benefits of fluoridated water. However, year-to-year, there continues to be small percentage increases. Considering the current rate of fluoridation activity, we project that by 1990

almost 65 percent of the population on public water systems will have access to fluoridated water, although the 1990 Objectives of the Nation's goal is 95 percent. Clearly, more emphasis needs to be placed on fluoridation activities in order to progress toward achieving national goals and improving the oral health of the Nation. It should be noted that a good indicator of progress in dental health is the incidence of dental caries, for which the goal established for 1990 has already been exceeded.

Question. How does CDC react to antifluoridation arguments offered by certain public interest groups?

Answer. Through continuing and comprehensive review of the relevant science on a worldwide basis, CDC retains the capability to respond to these types of inquiries. While a number of the concerns raised by individuals or groups are not new, we are still committed to being responsive to such inquiries by providing information from scientific studies that have examined the effectiveness and safety of water fluoridation.

IMMUNIZATION/DAY CARE CENTERS

Question. This Nation has achieved a remarkable level of immunization. To date, approximately 98 percent of children are immunized against the childhood diseases prior to entering school. There is growing concern, however, over the spread of certain diseases among preschool children in day care centers as the numbers of children in such day care center arrangements continue to increase.

How many States have established immunization requirements for day care attendance?

Answer. Most of the States (45) have laws which require children who attend licensed day care centers to be immunized against the childhood vaccine-preventable diseases of measles, mumps, rubella, diphtheria, pertussis, tetanus, and polio. As a result, immunization levels for this age group are high. Data from the 1984/85 day care surveys indicate immunization levels of 93 percent for polio and mumps, and 94 percent for measles, rubella, diphtheria, pertussis, and tetanus. These levels are 3-15 percentage points greater than the immunization levels of children who do not attend day care centers.

Question. What are the prospects for achieving a 98 percent immunization level for children in day care?

Answer. The 1990 objective for immunization levels in day care centers is 90 percent. We estimate that we have achieved the following levels in licensed day care centers: 94 percent for measles, rubella, and DTP; 93 percent for mumps and polio. Although these levels could improve, a level of 98 percent in any population will be difficult to reach and maintain.

IMMUNIZATION PROGRAM - COLLEGE LEVEL

Question. The elimination of indigenous measles expected a few years ago has not materialized, due in large part to discrete outbreaks, often on college campuses.

What are you doing to encourage States and communities to require immunizations for entry into college?

Answer. Each year, Public Health Representatives in all States are asked to provide a status report on the number of public and private institutions which include immunity to measles as a condition of registration/admission for their students and to promote the development of regulations requiring immunization in those institutions which don't have them. We currently estimate that for all institutions, a total of 413 (24 percent) of the universities/4-year colleges and 76 (7 percent) of the 2-year-colleges currently require measles immunity as a condition of registration/admission for their students.

Question. How many States have such requirements?

Answer. According to recently obtained information, 39 States have colleges that require immunity to measles as a condition of registration/admission. Of the 12,398,484 students enrolled in colleges, a total of 1,763,867 (14 percent) of the students are currently affected by these requirements.

Only the District of Columbia, Puerto Rico, and North Carolina have passed legislation requiring vaccinations as a condition of registration/admission for students attending both public and private institutions. Rhode Island has passed legislation specifying immunity to rubella for females as a college entry requirement, while South Dakota and Mississippi have measles immunity regulations, which only apply to students attending State-supported institutions.

Question. How many colleges?

Answer. For all institutions, a total of 413 (24 percent) of the universities/4-year colleges and 76 (7 percent) of the 2-year-colleges currently require measles immunity as a condition of registration/admission for their students.

CHILDHOOD IMMUNIZATION/SHORTAGES - GENERAL

Question. Dr. Mason, during the last six years, manufacturers of our childhood vaccines have steadily decreased in number where we now have only one U.S. producer of polio and measles-mumps-rubella (MMR) vaccine and only two U.S. producers of Diptheria-Tetanus- Pertussis (DTP).

What are your plans to: A) Keep current producers on the market; and B) Stimulate more companies to get into the vaccine business?

Answer. Several new sources of some of the childhood vaccines may be considering the market. In today's climate, it is difficult to stimulate new entries in the market for certain childhood vaccines where litigation and product liability costs are high. This is particularly true for current DTP used in the U.S. We are working with the FDA and manufacturers, to develop new, less reactogenic vaccines and to document the efficacy of these vaccines so that U.S. licenses can be granted.

The greatest threat to the supply of vaccines remains the liability issue. The Administration has transmitted legislation to the Congress last year to ban punitive and limit non-economic awards against vaccine manufacturers. We believe that this legislation, if enacted, would greatly reduce the threat of vaccine manufacturers leaving the market and could encourage other manufacturers to enter the market. This could not only reduce the probability of vaccine shortages, but also help contain the increasing cost of vaccine.

EPIDEMIC SERVICES -- USER FEES

Question. What has been your experience over the last year in the collection of user fees for providing certain laboratory services for commercial manufacturers and clinical laboratories?

Answer. We are just now implementing the user fees for providing certain laboratory services for commercial manufacturers and for providing proficiency testing to private clinical laboratories.

Question. What plans do you have for expanding the use of user fees in the future?

Answer. At the present time, we do not have any plans for the expansion of user fees.

Questions Submitted by Senator William Proxmire

BUILDING AND FACILITIES BUDGET

Question. Your request of $1.8 million under the Building and Facilities account is $3.6 million below current level. Tell us what these funds will support next year.

Answer. The increasing age of our facilities is requiring more repairs to keep the facilities operational. The $1.8 million will fund maintaining our buildings and replacing worn fixed equipment. Expected projects include roof replacement, replacing worn-out heating and air conditioning, removing architectural barriers, interior repair and painting, repairs to walls, electrical modification, street repairs, and laboratory improvements.

Question. What about the $1.9 million proposed for rescission? What improvements would you be able to accomplish if the proposed rescission is not adopted by Congress?

Answer. The $1.9 million proposed for rescission was planned to purchase scientific equipment for the new virology building under construction.

Question. How do these projects fit in with CDC's long range Master Facilities Plan?

Answer. The $1.9 million was to be used to equip the new virology building that was already funded prior to the long range

Master Facilities Plan and was part of the base on which the plan was based.

Question. Can you tell us briefly about the Plan?

Answer. The long range Master Facilities Plan is the result of a project to study the current CDC space utilization from a site, facilities, and operational perspective, and to develop a strategic implementation plan to address the present and projected space and operational needs identified in the study. The Plan was limited in scope to the Atlanta, Georgia facilities, including the Clifton Road site, Chamblee site, Lawrenceville site, and 4 areas of leased space.

The review of existing conditions focused on currrent space utilization between laboratories and other support and office needs of CDC's programs, the structural soundness of existing buildings and the state of their heating/ventilating/air conditioning and electrical systems, energy use, security, safety, and parking needs, and potential for further site development. The solutions recommended in the Plan will provide CDC management with a "roadmap" for setting priorities over the next 10-15 years as resources become available to address the identified facilities needs.

WORK RELATED INJURIES AND DEATH

Question. I'm interested in the incidence of work-related injuries and death mentioned on page 7 of your statement, Dr. Mason. You advise that approximately 1 out of every 10 employees in private industry suffers an occupational injury -- about 4 out of every 100 workers is disabled -- and about 7 out of every 100,000 workers are killed on the job. How do these figures compare with injuries and deaths over the last decade? Is the trend downward?

Answer. Yes, generally the trends are downward. However there are differences in the statistics available from the two primary sources of injury statistics we have been using, the Bureau of Labor Statistics (BLS) Annual Survey and the National Safety Council's Accident Facts, because they include different study populations and define their cases differently.

The BLS defines an occupational injury as an injury which involves loss of consciousness, restriction of work or motion, transfer to another job, or medical treatment (other than first aid) and results from a work accident or from exposure involving a single incident in the work environment. They define disabling injuries (lost workday cases) as cases involving days away from work or days of restricted work activity or both. They define an occupational fatality as a death associated with the workplace, regardless of the time between the injury and death. The Annual Survey excludes self-employed individuals, farmers with fewer than 11 employees, employers regulated by other Federal safety and health laws, and Federal, State, and local government agencies.

Injuries: the BLS statistics on injuries show a downward trend from 10.5 injuries per 100 workers in 1972 to 7.8 per 100 workers in 1984.

Disabling Injuries: the trend for disabling injuries is not clear. It increased from 3.2 injuries per 100 workers in 1972 to a peak of 4.2 injuries in 1979. Since 1979 the trend has been generally downward. There were 3.6 disabling injuries per 100 workers in 1984.

Fatalities: the statistics on fatalities show a downward trend from 7.6 fatalities per 100,000 workers in 1972 to 4.7 fatalities per 100,000 workers in 1984.

The National Safety Council (NSC) defines a disabling injury as one which results in death, some degree of permanent impairment, or renders the injured person unable to effectively perform his regular duties of activities for a full day beyond the day of the injury. An occupational fatality is defined as a death which occurs within one year of an accident on the job. Workers are all persons gainfully employed, including owners, managers, other paid employees, the self-employed, and unpaid family workers, but excluding domestic servants.

Disabling Injuries: the NSC statistics on disabling injuries show a downward trend from 2.9 disabling injuries per 100 workers in 1972 to 1.8 disabling injuries per 100 in 1984.

Fatalities: the statistics on fatalities show a downward trend from 17 deaths per 100,000 workers in 1972 to 11 deaths per 100,000 workers in 1984.

Question. Have you recommended any new standards to the Department of Labor to protect employees in high risk occupations?

Answer. Since July 1981, NIOSH has submitted 9 recommendations for standards (criteria documents) to the Occupational Safety and Health Agency (OSHA). In addition, NIOSH has submitted 42 responses to OSHA concerning OSHA regulatory actions. These recommendations apply to working conditions for numerous occupations. For instance, in 1984 we submitted a criteria document to OSHA which covers occupational safety and health hazards associated with the various operations involved in the manufacture of paint and allied coating products. In 1985, we submitted a criteria document to OSHA giving recommendations for controlling occupational safety and health hazards associated with the various operations conducted in foundries. Below is a list of the 9 criteria documents submitted since July 1981:

1. Criteria for Controlling Occupational Exposure to Cobalt

2. Development of Draft Construction Safety Standards for Excavations

3. Criteria for a Recommended Standard ... Occupational Exposure to Styrene

4. Recommendations for Control of Occupational Safety and Health Hazards ... Manufacture of Paint and Allied Coating Products

5. Occupational Safety in Grain Elevators and Feed Mills

6. Guidelines for Controlling Hazardous Energy During Maintenance and Servicing

7. Comprehensive Safety Recommendations for Land-Based Oil and Gas Well Drilling

8. Comprehensive Safety Recommendations for the Precast Concrete Products Industry

9. Recommendations for Control of Occupational Safety and Health Hazards ... Foundries

DAY CARE CONTAGION

Question. I understand CDC is beginning a nationwide study of infectious diseases in day care facilities. Given the estimated 12 million children who now spend most or part of their days in such an environment, such an assessment is critical. Not only is day care responsible for at least 10 percent of all hepatitis A cases annually, but approximately 40 percent of bacterial meningitis now occur there. Have you given any consideration to mandating immunization of children attending these facilities?

Answer. Most of the States (45) already have laws which require children who attend licensed day care centers to be immunized against the childhood vaccine-preventable diseases of measles, mumps, rubella, diphtheria, pertussis, tetanus, and polio (H flu b vaccine was only licensed for use in April 1985 and States have not had an opportunity to include this vaccine in their requirements). As a result, immunization levels for this age group are high. Data from the 1984/85 day care surveys indicate immunization levels of 93 percent for polio and mumps and 94 percent for measles, rubella, diphtheria, pertussis, and tetanus. These levels are 3-15 percentage points greater than the immunization levels of children who do not attend day care centers.

Since the States have been able to obtain such high immunization levels in day care centers, we feel it is unnecessary and inappropriate for the Federal government to enact legislation in this area. However, we will continue to encourage those States who do not have day care immunization requirements to enact such laws and those who do to continue to enforce them.

SEXUALLY TRANSMITTED DISEASES

Question. Dr. Mason, perhaps you can clarify some confusing information regarding the status of CDC's chlamydia control program. Page 29 of your budget justifications clearly indicates that support of this activity would continue to be increased next year. However, based on the Department's report covering its Gramm-Rudman-Hollings cuts, the $4.2 million to be taken out of the Sexually Transmitted Diseases Program will "...affect further implementation of a national chlamydia control program .... and projects aimed at developing cost-effective methodologies for the control of chlamydia will be reduced..." Just how much will be spent under this activity during the current fiscal year?

Answer. In FY 1986, our estimate is that grant funds expended for chlamydia will be approximately $4.5 million and direct operation funds $1.3 million, or $100,000 more than was spent in FY 1985. Funds allocated for the sexually transmitted disease program to date have not specifically addressed a nationwide chlamydia prevention and control program. However, because of the serious public health consequences for both mothers and infants infected with chlamydia, the CDC has over the past two years restructured priorities and placed increasing emphasis upon the development of effective prevention and control programs for chlamydia. This increased emphasis will continue in FY 1986 within the limitations of Gramm-Rudman-Hollings cuts. The original FY 1986 appropriation included an increase of approximately $1.3 million over the FY 1985 level. CDC intended to use the entire amount on the expansion of a nationwide chlamydia prevention and control effort. The reductions required by Gramm-Rudman-Hollings amounted to $2.4 million for the Sexually Transmitted Disease Program, which will compromise - but not totally negate - our ability to increase activity in the area of chlamydia control.

Question. How does that compare with fiscal years 1984 and 1985?

Answer. In FY 1984, $2.1 million in grant and $1.8 million in direct operation funds were spent. In FY 1985, $4.4 million in grant and $1.3 million in direct operation funds were directed to chlamydia.

Question. What's the estimate for fiscal year 1987?

Answer. In FY 1987, an estimated 10 percent of grant funds or $4.6 million will be directed to chlamydia prevention and control. Direct operation funds, which have included several research and demonstration projects, will be approximately the same level as in 1986.

AGENT ORANGE STUDY

Question. The budget justifications briefly mention CDC's interagency agreement with the Veterans Administration in connection with its Vietnam veterans health studies. I understand the Office of Technology Assessment has been rather critical of CDC's protocol in the Agent Orange study. Why does OTA continue to be concerned over this issue and when do you think it will be resolved?

Answer. The Office of Technology Assessment's primary concern relates to the issue of exposure assessment for the Agent Orange study component. Two key issues which need to be resolved are: (1) whether the data contained in military records is complete enough to allow a precise assessment of exposure to agent orange, and (2) are there sufficient number of men with a high opportunity for exposure. CDC anticipates these issues will be resolved by May or June 1986.

IMMUNIZATION PROGRAM

Question. The Gramm-Rudman reductions under program operations will postpone CDC's yearly Immunization Survey. What impact will this have on your future planning?

Answer. When the United States Immunization Survey (USIS) was first conducted, it was the sole measure of the estimated immunization level for the Nation. It is based on a national probability household survey that is conducted by the Bureau of the Census. Approximately 90 percent of the data produced by the USIS pertains to the assessment of the childhood immunization status and 10 percent to the assessment of adult immunization status.

As the immunization program was developed, the need for more accurate assessment of childhood immunization levels by State was recognized. Therefore, a complementary system was proposed to and accepted by the grantees which becomes a part of their required grant supported activities. Now all State health departments collect immunization information for children when they enter the school system. All States have laws requiring all children to have basic immunization series, appropriate for age, to attend schools. This information is usually based on a verifiable immunization record that is presented by the parent or guardian to school officials, and is our most reliable indicator of immunization status. Information based on a subset of the total sample of USIS data (i.e., reference to an immunization record) is generally within about 10 percentage points of comparable data collected through the States' system for comparable ages. This subset is also believed to be a more accurate indicator of the immunizations status of the younger preschool children, but still subject to error.

Therefore, the school-aged childhood portion of the USIS is a less accurate indicator than the complementary data set collected by the States.

The two areas where the USIS provides important data which is not uniformly collected at the States grantee level are the assessment of adult immunization levels and the assessment of immunization levels in the preschool population. With respect to the preschool population, the State grantees collect several data sets on subgroups of this population such as those attending licensed day care facilities, head start programs, EPSDT, etc. These data sets provide indicators of the immunization status of the preschool population.

However, the USIS provides an important major and only source of national data on adult immunization status. A complementary set of information on the net distribution of certain adult antigens remains available through CDC's Biologics Surveillance Program (BSP). The BSP is a system that monitors the net distribution of the national market of the major biologicals. While the information provided by this system is valuable, information on actual immunization status acquired through the USIS, would allow more focused planning efforts in adult immunization.

We are working to develop new and more efficient methods to assess the status of immunization status. We hope that we can continue the operations of the program as effectively as ever.

NEW LEGISLATIVE PROPOSALS

Question. Are you proposing any new initiatives or modifications to existing law? If so, please tell us briefly about them.

Answer. No, CDC has not submitted any legislative proposals for 1987.

USE OF ANIMALS

Question. For the record, please advise the extent to which CDC uses animals. What I'm looking for is a breakdown showing the number and species used last year, for example, the justification for their use, whether your animal facilities are accredited by the American Association for Accreditation of Laboratory Animal Care.

Answer. CDC's research and diagnostic programs involve the use of a large number of animals representing more than 20 species. The tabular material below presents a typical daily inventory of the animals maintained at CDC's Atlanta area facilities during FY 85.

Armadillos	30
Cattle	10
Chimpanzees	25
Dogs	170
Ferrets	50
Fowl	400
Foxes	10
Gerbils	300
Goats	60
Guinea pigs	400
Hamsters	200
Horses, Burro	3
Mice	58,200
Mongooses	10
Monkeys	500
Opossums	2
Rabbits	2,500
Raccoons	20
Rats	700
Sheep	50

CDC maintains active research programs in a variety of infectious disease areas where vaccine development, chemotherapy, pathological mechanisms, diagnostic techniques, and the isolation and identification of infectious agents are primary areas of concern. In addition, studies on potential environmental toxins require the use of experimental animals. The varied nature of these studies helps to understand the number of animal species involved since the species, age, and sex of experimental animals used must be carefully selected to fill the needs of specific programs.

The CDC Atlanta area animal care facilities have been AAALAC accredited since 1967.

Question. What steps have been taken over the past two years to reduce the number of animals used?

Answer. A protocol review is completed for every project requiring the use of laboratory animals. As a part of this review, each investigator must indicate that research techniques other than the use of experimental animals have been explored for the particular project. This review process and management control of increasingly expensive laboratory animal procurement, care, and maintenance are expected to reduce the number of animals used at CDC.

Question. Dr. Mason, I'm curious about CDC's Advisory Committee activities. You obligated $52.6 thousand for these services last year and estimate twice that amount this year and in fiscal 1987. Tell us what these Advisory Committees do and how they differ from services rendered by consultants.

Answer. We have four Federal advisory committees at CDC. These committees provide advice and guidance to the Secretary, the Assistant Secretary for Health, the Director, CDC, and the Director, National Institute for Occupational Safety and Health (NIOSH), concerning the following:

1. The Board of Scientific Counselors, NIOSH, provides advice and guidance on NIOSH research programs. Specifically, the Board provides oversight of the Institute's research program to ensure scientific quality, timeliness, utility, and dissemination of results.

2. The Immunization Practices Advisory Committee addresses issues regarding the most appropriate application of antigens and related agents (e.g., vaccines, antisera, immune globulins) for effective disease control in the civilian population. Additionally, this Committee reviews and reports regularly on immunization practices and recommends improvements in the national immunization efforts.

3. The Mine Health Research Advisory Committee advises on matters involving or relating to coal or other mine health research, including grants and contracts for such research. It provides a peer review function in assessing health research needs and advises on agency program functions.

4. The Safety and Occupational Health Study Section advises and makes recommendations on scientific, research, and training needs related to occupational safety and health which are in need of special emphasis and on the competency available to meet such needs. The Study Section provides review for scientific and technical merit of all research, training, and demonstration grant applications, and fellowships in the program areas related to the cause, prevention, and

control of diseases and injuries in the occupational environment. It makes recommendations to appropriate national advisory councils and the Director, NIOSH, as to grant applications which merit support.

The major difference between the use of committees and services rendered by consultants is that when a committee is utilized, we have the benefit of collective or consensus advice and recommendations on the subjects which the committees address. When consultants are utilized, we can only obtain individual, independent advice and recommendations. Attempting to deal independently with individual consultants can be time consuming and inefficient. This method would not be feasible when dealing with the complex issues addressed by our committees.

Question. What are the funds used for?

Answer. These funds cover compensation for non-Federal members and nonmember consultants.

Questions Submitted by Senator Robert C. Byrd

CLINICAL RESPIRATORY FACILITY

Question. Dr. Mason, two divisions of the National Institute for Occupational Safety and Health are located in Morgantown, West Virginia. That facility is of primary importance to the research being done on respiratory diseases of coal miners and, as you know, is the national depository for x-rays of those suffering from black lung disease.

The Committee noted, in the report accompanying the Fiscal Year 1986 Appropriation Bill, that you were undertaking a feasibility study for the design and implementation of a clinical respiratory facility. How are you progressing on that study?

Answer. NIOSH plans to contract this fiscal year for the feasibility study on developing a clinical respiratory center. We have budgeted $150,000 for this purpose.

RESPIRATORY CERTIFICATION PROGRAM

Question. Dr. Mason, the National Institute of Occupational Safety and Health has a mission to identify and characterize current workplace conditions that cause disease or cause injury and to recommend strategies for prevention.

NIOSH also has a responsibility of certifying protective equipment. One aspect of that program is the certification of respirators. This is, of course, vital to our Nation's coal miners.

I would say that NIOSH, without question, leads the way in its research and certification program on respirators. As a matter of fact, because of the recognized expertise of NIOSH, a cooperative training and research effort with the Air Force and the Appalachian Laboratory on Occupational Safety and Health is

being negotiated. What is the current status of those negotiations?

Answer. On June 24, 1985, NIOSH provided the U.S. Air Force with a proposal to conduct an externship program at NIOSH for Air Force personnel. In this program, the Air Force would assign personnel to work in four NIOSH programs for a period of up to 2 years. These programs are:

1. Respirator Certification
2. Respirator Research
3. Field Evaluation of Respirator Performance
4. Chemical Protective Clothing

On September 17 and October 4, 1985, the Director of the Division of Safety Research (DSR) at NIOSH met with Air Force program officers to discuss the proposal. In the October 4 meeting with the Air Force Liaison Office, the Air Force representatives indicated that they were considering assigning Air Force personnel to the proposed externship program during FY 1986. We are awaiting their decision.

TRANSFER OF RESEARCH INFORMATION

Question. I just want to say that it makes good sense for federal agencies to share their expertise. Too often we put federal dollars into a program and the technology and expertise that is developed is not transferred and then in some other branch of government, we try to reinvent the wheel.

I certainly commend you for this cooperative effort, and I would hope that you will keep me apprised.

Could you tell me what NIOSH is doing to insure that the findings of its research is transferred not only to other pertinent federal agencies but also to the private sector?

Answer. NIOSH disseminates its research findings through numerous mechanisms The following is a brief outline of our activities:

- o Transferring Information to other Federal Agencies

  NIOSH directly provides all scientific reports published to OSHA, MSHA, and EPA. We also transmit NIOSH regulatory policy recommendations to these agencies to support their activities.

  NIOSH directly provides the results of all of its Health Hazard Evaluations to the appropriate OSHA regional office.

- o NIOSH Publications/Mailing List

  NIOSH publications are distributed in response to requests for them resulting from publications announcements made to approximately 17,000 occupational safety and health professionals. Availability of NIOSH publications is further publicized by secondary sources

such as professional, industry, and labor associations to their constituents. During FY 1985, publications were distributed in response to 17,000 letters and 7,500 telephone calls. NIOSH publications have also been reprinted by commercial publishers, thus increasing distribution of this material. The Government Printing Office and the National Technical Information Service also provide most NIOSH publications for sale.

Over 30,000 copies of the latest edition of the NIOSH Publications Catalog have been distributed worldwide. This Catalog contains information on the availability of NIOSH-numbered publications, Hazard Evaluation and Technical Assistance reports, industry-wide study reports, contract reports, grant reports, and other reports. Also, bibliographies of publications on specific topics are distributed through our mailing list, in response to requests, and at NIOSH exhibits at scientific and professional association meetings.

o NIOSH Data Bases

NIOSHTIC, the Institute's computerized bibliographic occupational safety and health information retrieval system, now contains over 120,000 records. Information is selected for this data base from appropriate English language scientific literature in such areas as epidemiology, pathology, toxicology, engineering control, behavioral sciences, occupational medicine and nursing. NIOSHTIC is made commercially available in the United States, Canada, Europe, Australia, Japan, and Korea from DIALOG Information Services and Pergamon InfoLine.

The NIOSH Registry of Toxic Effects of Chemical Substances (RTECS) contains toxicity data on more than 70,000 chemical substances and also contains additional data such as synonyms for the chemical substances, relevant occupational health regulations and NIOSH and ACGIH recommendations. RTECS is available for computer searching through the National Library of Medicine's MEDLAR system and from two other commercial vendors. It is also available as a quarterly Government Printing Office microfiche subscription, in book form, and on computer tape.

o Responses to Technical Information Requests

We respond to requests for occupational safety and health information from employees and external sources including other Federal, State, and local governmental agencies, academia, industry, labor organizations, and private consultants. In Fiscal Year 1985 we processed approximately 5,000 internal and external requests for technical information.

o Research Networks

NIOSH participates in the Federal Laboratory Consortium (FLC) and the Center for Utilization of Federal

Technology (CUFT). These networks enable scientists among Federal, State, university, and private research groups to share information on their current activities and findings.

o International Dissemination Activities

NIOSH is the U.S. Center for CIS, the International Labor Organization's 36-nation occupational safety and health information network. As such, NIOSH provides all of its material to the CIS data base for dissemination throughout the world. We also exchange information on current research with six research institutes in five countries, and we exchange publications with thirteen research institutes in nine countries. Additionally, formal translation exchange agreements exist with the United Kingdom, Australia, and Canada, and NIOSHTIC exchange agreements exist with Canada and Sweden.

Approximately 12 percent of requests for our publications were from foreign sources.

ALOSH SCIENTIFIC AND SUPPORT COSTS

Question. Dr. Mason: Would you supply for the record, a breakdown of the number of support and scientific personnel and research projects and the dollar costs associated with those activities at the Appalachian Laboratory on Occupational Safety and Health for Fiscal Years 1985, 1986, and projections for Fiscal Year 1987?

Answer. Following is a breakdown for the Appalachian Laboratory for the Fiscal Years 1985, 1986, and 1987:

	1985	1986	1987
Support Personnel:	87	90	80
Scientific Personnel:	141	147	145
Research Projects:	110	110	110
Dollar Costs:	$10,014,761	$8,790,270	$9,405,000

Question. Would you also include in that same report, research or any other activities, including publications, that will be delayed or dropped.

Answer. Activities at the Appalachian Laboratory that will be delayed, reduced or cancelled are listed below:

Cancelled Activities

1. Traditional Personal Protective Equipment

2. Physiological Response Project - Phase III - Cooling Garment Effectiveness.

Delayed or Reduced Activities

1. The National Occupational Health Survey of Mining (NOSHM) project field activity will be continued at 66 percent of planned survey rate; therefore, completion of this project will be delayed by 1 year.

2. We will reduce site visits in the National Study of Coal Workers Pneumoconiosis from 12 sites in 5 states to 7 sites in 4 states.

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

STATEMENT OF ROBERT L. TRACHTENBERG, ACTING ADMINISTRATOR

ACCOMPANIED BY:

SHERVERT H. FRAZIER, DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH

LORAN D. ARCHER, ACTING DIRECTOR, NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

ELAINE N. JOHNSON, ACTING DEPUTY DIRECTOR, NATIONAL INSTITUTION ON DRUG ABUSE

KENT AUGUSTSON, DIRECTOR, FINANCIAL MANAGEMENT

INTRODUCTION OF ASSOCIATES

Senator HARKIN. Our next witness is Mr. Robert L. Trachtenberg, the Acting Administrator of the Alcohol, Drug Abuse, and Mental Health Administration [ADAMHA], and he is accompanied by several people I hope you will introduce for the record. I understand also that Dr. Frazier will also testify in behalf of the fiscal year 1987 budget request for St. Elizabeths. So welcome to the committee, Mr. Trachtenberg, and please introduce your people and proceed as you wish.

Mr. TRACHTENBERG. Thank you, Mr. Chairman, I am very pleased to be here this morning. With me, on my far right is the Acting Director of the National Institute on Alcohol Abuse and Alcoholism, Mr. Loran Archer. Next to him is the Director of the National Institute of Mental Health [NIMH], Dr. Shervert Frazier. Immediately to my left is the agency's Financial Management Officer, Kent Augustson, and next to Kent is Ms. Elaine Johnson, who is the Acting Deputy Director of the National Institute on Drug Abuse [NIDA].

PREPARED STATEMENT

With your permission, Mr. Chairman, I would like to submit my formal statement for the record and give you a brief summary of what is contained in that statement.

[The statement follows:]

STATEMENT OF ROBERT L. TRACHTENBERG

I am pleased to appear before you as Acting Administrator of the Alcohol, Drug Abuse, and Mental Health Administration, to discuss the President's Fiscal Year 1987 budget request for activities dealing with these public health problems, which together cost the Nation an estimated $249 billion in 1983.

Mr. Chairman, even that exorbitant sum--which encompasses health care expenses, reduced productivity, costs of accidents and violence related to alcohol, drug, and mental health problems, and many other direct and indirect expenses--cannot take into account the personal suffering and individual tragedies attributable to these problems. Alcohol abuse contributes to a wide range of impairments and disease, including physical, mental, and emotional disorders. Alcohol is involved in 100,000 deaths annually in the U.S. and is strongly associated with traumatic injuries, the leading cause of death and disability for persons under 44. About one-third of the American household population has tried an illegal drug, and many thousands of persons -- young and old alike -- have drug abuse problems. A 1985 survey of high school seniors found that 17 percent-- the highest proportion ever--have used cocaine, the most powerfully addictive drug known. And recent surveys have shown that one out of every five of our citizens has a diagnosable mental health problem in any six-month period.

Fortunately, we are making steady progress toward prevention and treatment of these disorders through modern research programs that range from studies of etiology to development of treatment and prevention approaches. In fact, some of the most important research findings in the entire health field today are being uncovered by alcohol, drug abuse, and mental health scientists.

In mental health research, for instance, we are beginning to

understand the chemical and molecular genetic function of the brain, and to find the physiological bases of such widespread and chronic diseases as schizophrenia and Alzheimer's disease. Significant progress has also been made in uncovering physiological factors in such functions as memory, cognitive processes, and sleep.

Drug abuse research also has realized many important advances, including the well-recognized breakthrough in identifying and elucidating opiate receptors and peptides in the brain. Another recent accomplishment is the beginning development of the first effective treatment regimen for cocaine users.

In alcohol research, the importance of the genetic contribution to alcoholism has been more firmly established, and new recombinant DNA methods are being employed to uncover the genetic mechanism involved. Other recent NIAAA research has made it increasingly clear that alcohol has adverse effects on the immune system.

Mr. Chairman, the President's budget for fiscal year 1987 would allow the Nation's march of progress against ADM problems to continue. The request seeks to maintain approximately the same current program level of funding as available in 1986, after the sequestration required by the Balanced Budget and Emergency Deficit Control Act of 1985.

The primary approach to maintaining this level of research activity would be establishment of 1,400 as the total number of investigator-initiated research project grants to be funded in 1987 and beyond. This total, along with maintaining the intramural research efforts of the three ADAMHA Institutes at their 1986 funding levels, would permit the agency to continue its most vital research within current fiscal restraints of the Federal budget.

The President's request for ADAMHA programs in 1987 is $892.2 million, including $318.9 million for research, $18.5 million for

research training, $490 million for support of State services through the block grant program, and $7.4 million for program management. The total request represents an increase of $16.8 million over 1986, after sequestration of $42 million, and proposed rescissions of $40 million from the 1986 NIMH appropriation.

Proposed rescissions include $19 million for the NIMH clinical training program and $11 million for its community support programs. In part because of past Federal support for clinical training, a shortage of mental health professionals no longer exists. Community support demonstration grants have now been awarded in all States, and successful models can be replicated using block grant funds. Also included in the rescission is $10 million appropriated in fiscal year 1986 for a new mental health protection and advocacy program. The program would duplicate the States capacity to protect mentally ill persons from abuse and neglect.

Excluded from the President's request for ADAMHA is $13 million for AIDS research and technical assistance which are budgeted in the Office of the Assistant Secretary for Health to allow optimal coordination of all AIDS activities across the Public Health Service. Under this arrangement, ADAMHA would be reimbursed by PHS for research and other expenditures related to this crucially important disease.

Mr. Chairman, because development of new knowledge to reduce and prevent ADM problems is the pre-eminent purpose of our agency, I would like to devote the rest of my statement to describing briefly some research directions the ADAMHA Institutes would take in 1987 under the President's budget.

The request for mental health research in FY 1987 is $194.9 million. The Institute would assign special priority to areas such as schizophrenia, disorders of children and adolescents, mental

health of the aging, and research in the basic sciences. The budget request increases the percentage of funds for each of these areas, selected on the basis of current scientific opportunities and the urgent need to expand knowledge related to them.

In research on schizophrenia, for instance, scientific investigators would continue the search for the causes of this illness and for potential predictors of treatment response and methods to prevent relapse. The heterogeneity of findings on schizophrenia has convinced researchers that this is not a single disease with a single cause. Based on that conclusion, NIMH in 1987 would launch a major effort to identify subtypes of the illness.

NIMH also would pay particular attention in FY 1987 to research on preventing impulsive behaviors such as suicide, which is a serious and growing problem among our teenagers. This effort would include studies of risk factors and of early diagnosis and treatment of depression in youth, known to be a key to many of these deaths.

In related activity, the Institute plans a major effort in 1987 to disseminate the considerable store of knowledge it has developed about the etiology, diagnosis, and treatment of depression. This effort--to be known as Project DART (Depression Awareness, Recognition, and Treatment)--is deemed necessary since, although depression is the most treatable of the major mental disorders, only one in five of its more than nine million victims currently seeks treatment. Furthermore, many general practitioners now lack the knowledge and skills they need to identify and treat patients who are suffering from this illness.

NIMH also would continue its current research activities aimed at understanding psychobiological and psychosocial aspects of AIDS.

The President's request for drug abuse research in FY 1987 is $67.4 million, an increase of $2 million over the revised 1986

level. This increase would support slightly expanded research activity across the full spectrum of scientific work underway in National Institute on Drug Abuse programs to learn more about many drug problems now harming our citizens, in particular our youngsters. The 1985 high school survey showed a leveling off of the previous 5-year downward trend in use of several drugs, an adverse development which bears close watching.

In 1987, drug abuse studies would include development of further understanding of how drugs act upon the brain, and of the precise cellular and central nervous system mechanisms involved. Additional research also would be conducted on the behavioral effects of drugs, and on the risks and consequences from drug abuse. For example, the number of people admitted to hospital emergency rooms following cocaine use increased 300 percent between 1980 and 1985. Increases of this magnitude are rare in public health areas, but quite common in the drug abuse field.

NIDA also would continue its vital research to find new treatment approaches for drug abuse. While much is known about how to treat narcotic users, and progress has recently been made toward developing treatment for cocaine abusers, very little is known about how to treat PCP and marijuana users. Developing treatment programs for these drugs, and for adolescents, would be priorities in 1987. The Institute also would direct its attention to the question of "cost effectiveness" of various treatment approaches, a point of ever greater concern as local treatment programs face increasingly stringent fiscal conditions.

A further priority would be on finding alternative data collection techniques to expand the range of information we gather on incidence and prevalence of drug abuse. There is constant fluctuation in the number of people using illicit drugs across the

U.S., and in the ways they use them. While current information collection systems such as the National High School Survey represent dramatic improvements in data gathering since the drug abuse epidemic first hit our Nation, they are expensive and do not provide information on certain important groups in the population, such as high school dropouts, college students, and the homeless. NIDA would continue its search in 1987 for relatively inexpensive and rapid methods for obtaining improved information on drug trends.

NIDA research on AIDS would attempt to clarify the epidemiology and natural history of HTLV-III infection among intravenous drug users -- the second highest population at risk--and determine if drug use alters the course of the disease once it is contracted.

Another priority activity for NIDA in 1987, Mr. Chairman, will be to assist private organizations, companies, and schools in their efforts to combat drug abuse. The willingness of citizens at the grass roots to join the fight against drug abuse is one of the most encouraging developments of the 1980's, and we will do our utmost to continue to provide them technical support.

Under the President's request of $57 million for alcoholism research in FY 1987, the National Institute on Alcohol Abuse and Alcoholism would continue its scientific work to elucidate the genetics of alcoholism. It is increasingly evident that heredity is a major contributing cause of alcoholism and promising leads on genetic markers of this disease are beginning to emerge. Research in this area would include examination of genetic variations in the enzymes of alcohol metabolism, the structure and function of nerve cells, and electrophysiological traits.

The scheduled completion of the NIH centralized nuclear magnetic resonance (NMR) facility would allow an expansion of NIAAA's intramural studies into the effects of alcohol on the cell

and the mechanisms by which alcohol produces intoxication, tolerance, and physical dependence. NMR technology also will be used to gain a better understanding of alcohol's effects on the structure and function of the brain and to develop methods for early identification of alcohol induced brain damage. Brain dysfunction is present in a high percentage of alcoholics, and organic brain syndrome associated with chronic alcohol abuse is second only to Alzheimer's disease as a cause of adult dementia.

The NIAAA also would place a major emphasis in 1987 on treatment research to address pressing questions on patient placement, such as the relative efficacy of different therapies ranging from detoxification to aftercare, appropriateness of inpatient versus outpatient treatment settings for different types of patients, and optimum length of stay in residential facilities.

Another NIAAA research emphasis in 1987 would be alcohol-related trauma, including studies to determine the influence of alcohol on severity of injury, the body's ability to recover, and interactions with medications commonly used in treatment of trauma. Research also would be pursued on alcohol and pregnancy, new prevention approaches, and alcohol-related medical disorders. The effects of alcohol on the immune system, particularly on resistance to AIDS, would receive special attention in 1987.

The President's 1987 budget request includes $490 million for Alcohol, Drug Abuse, and Mental Health Services block grants, $21 million over the amount available in 1986. The grants provide the States the flexibility to plan, implement, and control their own alcohol, drug abuse, and mental health services to best meet their communities' identified needs.

Biography of Robert L. Trachtenberg

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Business Phone: (301) 443-4795

Date of Birth: February 17, 1937
Place of Birth: Brooklyn, New York

Married - 4 children

Fairleigh Dickinson University - 1957 - B.A.
New York Law School - L.L.B. - 1959 (Law Review)
Admitted to practice in New York State and Washington, D.C.

11/85 to date - Acting Administrator, ADAMHA, PHS, DHHS.

7/84 - 11/85 - Returned to former position as Deputy Administrator, Alcohol, Drug Abuse and Mental Health Administration, Public Health Service, Department of Health and Human Services.

9/83 - 7/84 - Acting Administrator, ADAMHA, PHS, DHHS.

7/82 - 9/83 - Deputy Administrator, ADAMHA, PHS, DHHS. Acts as alter ego to Administrator of the agency and serves as Acting Administrator when necessary, carrying out such public and internal functions as necessary; supervised the internal management of the Office of the Administrator to assure responsiveness to workload requirements, and satisfy requirements of the Assistant Secretary for Health and the Department. Assists in developing and implementing management and program systems and procedures to comply with agency policy priorities. Maintains continuing oversight of Institute activities to develop current awareness of key issues and to assist the Institute Directors in developing sound Institute policy.

10/81 - 7/82 - Acting Director, Office of Community Services, DHHS. At the request of the Secretary, DHHS, on temporary assignment to establish and administer multi-faceted program of State block grants, discretionary programs and closeout of former CSA programs. Implemented creative fiscal, audit, and grants management practices to accomplish closeout of major anti-poverty agency. Demonstrated success in recovering large sums of Federal dollars from grantees.

5/79 - 10/81 - Deputy Administrator, ADAMHA, PHS, DHHS. As Deputy Administrator, shared with the Administrator the responsibility for planning, managing, and providing the overall direction necessary for effective accomplishment of ADAMHA programs and activities. Particular focus was on development of management accountability systems and the setting of program of priorities for expenditure of $750 million annual budget.

1/75 - 5/79 - Associate Commissioner for Hearings and Appeals and Chairman of the Appeals Council for the Social Security Administration. Directed a 4,500 person organization. Was responsible for providing program and management direction over a decentralized hearings program and centralized appellate system. Employed over 650 administrative law judges. OHA is one of the largest systems of administrative justice in the Federal Government and one of the largest employees of attorneys.

9/73 - 1/75 - Deputy Assistant Secretary for Grants and Procurement Management in the Office of the Secretary, Department of Health, Education and Welfare. Developed, promulgated and enforced all procurement and grant regulations and policy for the DHEW, including cost and audit policy and minority business. Supervised contractor protest procedures. Also monitored and evaluated performance of the more than 200 grant and procurement offices within the Department.

8/67 - 9/73 - Office of Economic Opportunity, Deputy General Counsel. Served in a variety of supervisory positions in the General Counsel's office, culminating with Deputy General Counsel. Specialized in procurement and grant law and all facets of legal and business management, including supervision of OEO's investigative operations.

7/60 - 8/67 - Department of the Army. Served in various positions in the Department of the Army, including 4-1/2 years in the Judge Advocate General's Corps and as a civilian trial attorney. Specialized in government procurement law, business and administrative law matters.

AWARDS:

Recognition Award, William A. Jump Foundation	1974
Secretary's Citation, HEW	1975
Commissioner's Citation, Social Security Administration	1976
Secretary's Citation, HEW	1977
Commissioner's Citation, Social Security Administration	1978
Member, Administrative Conference of the United States	1975-1979
Senior Executive of Meritorious Rank Awarded by the President	1980
Senior Executive of Distinguished Rank Awarded by the President	1982
The Roger W. Jones Award for Executive Leadership	1985

OPENING REMARKS

Mr. TRACHTENBERG. Our fiscal year 1987 budget is basically consistent overall, particularly with respect to research, with our fiscal year 1986 revised budget. It will permit us to fund approximately 1,400 total grants, approximately the same as we did in fiscal year 1986, or we will in fiscal year 1986.

It permits us to restore our intramural research budget to the 1985 level, but there will be some reductions in our other research mechanisms. We are pleased that the overall research budget maintains the fiscal year 1986 revised level.

We believe this is a recognition of the enormous costs to society caused by these diseases, and the richness of opportunities that are in these fields. Alcoholism, drug abuse, and mental illness cost this Nation in 1983 $249 billion. This includes health care expenses, reduced productivity, accidents, and violence related to these problems.

This says nothing about the enormous cost, Mr. Chairman, of the personal suffering of the individual or the families. We are making steady progress, I am happy to say, toward prevention and treatment of these disorders. Some of the most important research findings in the entire health field today are being covered by scientists who are focusing on the issues related to alcoholism, drug abuse, and mental health.

I would just like to touch very briefly on some of the areas that we will be pursuing in fiscal year 1987, to give you a sense of our expanding program areas. In mental health we are beginning to find the physiological basis of such widespread and chronic disease as schizophrenia and Alzheimer's disease. In schizophrenia, scientific investigators will

continue the search of the causes of the illness, for potential predictors of treatment response, and ways to prevent relapse. The variety of findings to date on schizophrenia has convinced researchers that this is not a single disease with a single cause. NIMH plans to launch a major effort to identify the subtypes of the illness schizophrenia.

The Institute also will focus on preventing impulsive behavior, such as suicide, which is a serious and growing problem among our young people. In 1987 drug abuse studies will include development of further understanding of how drugs act upon the brain and of the precise cellular and central nervous system mechanisms involved.

Additional research will also be conducted on the behavioral effects of drugs and on the risks and consequences from drug abuse. Mr. Chairman, the number of people admitted to hospital emergency rooms following cocaine use increased 300 percent between 1980 and 1985. Increases of this magnitude are rare in public health areas but quite common in the epidemic-like field of drug abuse.

NIDA also will continue its vital research to find new treatment approaches for drug abuse. While much is known about how to treat narcotic users, and progress indeed has been made toward developing treatment strategies for cocaine abusers, very little is known about how to treat polychlorinated biphenyls [PCP] and marijuana users.

Developing treatment programs for these drugs and for adolescents will be priorities in 1987. I want to emphasize one thing, Mr. Chairman, with respect to young people. That is that our 1985 high school survey shows a leveling off for the first time in an otherwise 5-year downward trend in the use of several drugs. I suggest that this bears serious attention by NIDA and other agencies.

The National Institute on Alcohol Abuse and Alcoholism [NIAAA] will continue its scientific effort to elucidate the genetics of alcoholism. It is increasingly evident that heredity is a major contributing cause of alcoholism and promising leads on genetic markers of this disease are beginning to emerge. Research in this area would examine the genetic variations in the enzymes of alcohol metabolism, the structure and function of nerve cells, and electrophysiological traits.

NIAAA will also place a major emphasis in 1987 on treatment research to address pressing questions on patient placement, such as the relative efficacy of different therapies, ranging from detoxification to aftercare. It will also look at the appropriateness of inpatient versus outpatient treatment settings for various kinds of people afflicted with alcohol problems and we will look at the optimum length of stay in residential facilities.

Another NIAAA research emphasis in 1987 will be the alcohol-related trauma, including studies to determine the influence of alcohol on severity of injury, the body's ability to recover, and interactions with medications commonly used in the treatment of trauma.

Mr. Chairman, in addition to these very brief areas I mentioned, all three Institutes will continue and expand their research into AIDS. NIMH will study the psychobiological and psychosocial aspects of this

devastating disease. NIDA will attempt to clarify the epidemiology and natural history of the AIDS infection among intravenous drug users; and NIAAA will study the effect of alcohol on the immune systems resistance to AIDS.

With that, Mr. Chairman, I would like to conclude the statement and offer ourselves for any questions that you may have.

Senator HARKIN. Thank you very much, Mr. Trachtenberg.

FUNDING FOR ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH RESEARCH

I am sorry, I am a little confused here now. According to the chart I have, we appropriated $956.1 million total for the Alcohol, Drug Abuse, and Mental Health Administration. Fiscal year 1987 is $892 million, that is $63.9 million less. Yet in your opening statement you said the President's budget for fiscal year 1987 would allow the Nation's march of progress on ADM problems—I assume you mean alcohol, drug, and mental problems—to continue. The request seeks to maintain approximately the same current program level of funding as available in 1986, after the sequestration of Gramm-Rudman-Hollings.

I am confused. How can you say that?

Mr. TRACHTENBERG. You are referencing the appropriated fiscal year 1986 level, which is reduced by a number of factors: a 4.3-percent sequestration across each of the budget line items, including research, research training, and block grants; and approximately $40 million in proposed program rescissions which include clinical training, the Community Support Program [CSP], and protection and advocacy.

After these adjustments, there is actually a $17 million increase in 1987, albeit due mainly to the $22 million increase in block grants that restores them to their 1985 level. Our most important item, the research budget, remains basically constant between the 1986 revised level and the 1987 President's budget.

Senator WEICKER. Will you yield, Mr. Chairman? How about 1987 as to 1985?

Mr. TRACHTENBERG. The 1,400 total grants is one of the highest levels we have been at. We will also be able to restore the intramural program to the 1985 level. The area where we are hurt in terms of total dollars is the comparison between 1985 and 1987 in other research mechanisms which includes research centers, developmental awards, and small grants.

But in the principal investigator-initiated grants, which is our first priority, we basically are doing all right. We are able to restore the intramural program to the 1985 level. Other research mechanisms, however, take approximately a 16-percent reduction.

Senator WEICKER. So what you are saying is 1987 is, what? Equivalent to 1985? Are we at 1985 levels, to put it another way?

Mr. TRACHTENBERG. In terms of total research project grants, yes, it is comparable. In terms of total research dollars, our 1985 actuals are somewhat less than the 1987 proposed.

Senator WEICKER. But roughly the equivalent.

Mr. TRACHTENBERG. Yes.

Senator WEICKER. It is nice to know the world stood still since 1985.

Senator HARKIN. I am also a little confused by your statement on page 4 where you talk about the special priority areas you are going to give to schizophrenia, to depression in teenagers, the increased problem with suicide. I can't find it right now, but I remember you saying this about teenagers.

You put a lot of emphasis on your support for mental health research. But again I notice of the $63.9 million less, from 1986 to 1987, $61 million comes out of mental health.

Mr. TRACHTENBERG. Well, not all research——

Senator HARKIN. I understand that.

Mr. TRACHTENBERG. The large rescissions that are proposed for protection and advocacy, clinical training, and the Community Support Program all occur within mental health.

PROTECTION AND ADVOCACY

Senator HARKIN. Last year, with the administration's support, this subcommittee provided $10 million to help assure that States establish and operate protection and advocacy systems for the mentally ill. You are now proposing this program for rescission. Why?

Mr. TRACHTENBERG. The President's budget is proposing it for rescission. I believe the basis for that is the fact that there is still no authorization for the program. I am not sure there is a dispute in terms of principle behind the program. Rather, as there is currently no authorization for the program, it was a policy decision that it be proposed for rescission.

Senator HARKIN. Yet the administration did support it. And we supported it. We put it in.

Mr. TRACHTENBERG. It was not proposed for rescission by ADAMHA. But I believe the reason for it was the fact there is no authority.

Senator HARKIN. You did not propose it?

Mr. TRACHTENBERG. That's correct.

Senator HARKIN. Could you also tell me what other cuts were made that you did not request?

Mr. TRACHTENBERG. As I recall, we did not request clinical training dollars.

Senator HARKIN. Mr. Trachtenberg, let me turn this around. What programs did you request that OMB denied, let me put it that way.

Mr. TRACHTENBERG. It was not so much the programs which we requested and that OMB denied. There have been some traditional programs which, for the last couple of years, have been proposed for rescission, with clinical training and CSP being the two most significant. With respect to the remainder of our budget the issue was not what was requested and what was denied, but rather the level of our request versus the level that was ultimately supported. That level was reduced slowly as it went through the review of the Public Health Service, the Secretary's Office, and then ultimately OMB.

Beyond clinical training, and to a certain extent the Advocacy Program, the issue is what we view as the research opportunities to be supported and expanded versus what we ultimately are able to do given the President's budget request.

Again I suggest that given the current fiscal environment, we felt satisfied to have an overall research budget that was comparable to the revised 1986 level.

Senator HARKIN. One of those areas is a Community Support Program.

Mr. TRACHTENBERG. Yes.

COMMUNITY SUPPORT PROGRAM

Senator HARKIN. There have been previous proposals to eliminate the Community Support Program. There is no funding in it for fiscal year 1987, proposed rescission for fiscal year 1986. These programs play an important role in demonstrating innovative approaches to assisting the chronically mentally ill to live outside institutions. Do you have any evidence that the States no longer need these funds?

Mr. TRACHTENBERG. I don't believe it is a matter of the States not needing the funds or that we are disenchanted with the program. To the contrary, the States can always use more dollars. Most States have received on the average about 4 years of funding for the program with some States having already received the full 5 or 6 years of funding originally expected. The amount of the funding is relatively small, it is about $130,000 to $140,000 per State.

The point is that the infrastructure is in place. If we eliminate these dollars, the capacity the States have to service the chronic mentally ill patient will remain. The value of the program has been demonstrated. It is a good, established program. The States have seen that and I think they have had enough years of experience that they will continue to provide these services.

Thus, our rationale for proposing the rescission is not that it is an inappropriate program but rather that it is now an appropriate time to turn the program over to the States.

Senator HARKIN. You have enough information from the States and you have talked to them, and obviously they always want more money, but then they really can turn this thing over right now?

Mr. TRACHTENBERG. I have not personally spoken to the States; I wouldn't suggest that I have. But it is hard to imagine a program that has generated as much additional dollars as this program has generated, has built as much of an infrastructure as it has to deal with the chronically mentally ill, that by pulling out $130,000 per State will, in fact, mean that this program will die. I don't believe it will.

Senator HARKIN. Is mental illness a State problem? Is it something that affects us nationally or just on a statewide basis?

Mr. TRACHTENBERG. I think it is jointly a Federal, State, and local problem, and a family problem.

Senator HARKIN. I just think that those States that are experiencing certain economic problems, dislocations right now, are States where you have a high incidence of suicide. Do you want to look at Iowa for a while? What is happening out there, the number of suicides, teenage suicides, child abuse, runaway children.

It never happened before in my State. We have a fairly conservative, stable population. But because of the economic calamity, everything just seems to be tearing apart. I was in front of a farm bureau group that came in yesterday, about 50 farmers and some spouses, and a farmer that I didn't know very well got up in front of the group to introduce me and had his written notes there. In introducing me he started talking about the problems and the farm, and then he said that last month he had had to sell some of his machinery at a cut rate, and then his voice started to break up and he said: I had to sell off 120 acres and my son, who farmed with me, has to get out of the farming business. And he broke down and cried in front of 50 farmers.

I am telling you that because here is a State where we see an increase in mental health problems, in Iowa. And we don't have the money. I mean, the State coffers just aren't there.

Research is fine, we all support research. But when you cut down on things like the Community Support Program and say that you can cut it an average of $130,000 per State. That is an average, right? I assumed that was an average. I can tell you that it will affect some of those States drastically.

Mr. TRACHTENBERG. I would not dispute the profound effects on individuals which result from the kinds of issues you have described. I would, however, point to our Block Grant Program which is supported in 1987 at $490 million, the same as the fiscal year 1985 level. The block grant provides funds to Iowa as well as all the other States. At the State's discretion some of these funds could be channeled to community mental health centers to continue some of the services the CSP Program is developing.

The point I wish to make is that our role is to initiate and develop programs which, when established can be turned over to the States in the most effective way possible. That is what we are trying to do in the CSP Program.

Senator HARKIN. What will happen to the programs if you are taking funds from the Community Support Program?

Mr. TRACHTENBERG. In terms of the chronically mentally ill patient, CSP dollars are not used for treatment but instead help to set up the capacity at the State and local levels for treatment activities to be coordinated and carried out. In effect, treatment services are only indirectly funded by CSP dollars. The programs that exist to treat these people will continue through block grants, through private funds, and a range of other mechanisms. As you know, the Federal dollars in all the ADM services are very small compared to the total provided by private organizations as well as State and local governments.

TEENAGE SUICIDE

Senator HARKIN. A couple more. Teenage suicide, tripled since 1958. Without getting into too much depth on it, just briefly what is the funding level request for that? Is that an area where you are increasing research money, is it being decreased? Can you tell me, I don't have the line item in front of me.

Mr. TRACHTENBERG. I would like Dr. Frazier to address it directly. I just want to say one thing. Former Secretary Heckler established a task force to look specifically at youth suicide, and Dr. Frazier is the chairman of that task force. It is a departmentwide activity and I think it is going to come up with some good results.

But in terms of specifics, I would like to turn to Dr. Frazier.

Senator HARKIN. Dr. Frazier?

Dr. FRAZIER. We have about $1 million a year in NIMH for research in teenage suicide. This amount is part of our $29 million budget for research in affective disorders and depression. About 65 to 70 percent of the teenagers who committed suicide had an affective disorder. Another 30 to 35 percent had some kind of social, personal, or reactive problem that was not a basic depressive illness.

The teenage suicide task force has three working groups. The first is charged with assessing risk factors; the second is looking at preventions and interventions; and the third is planning strategies for the future. That is essentially defining the areas in which we need to have more knowledge and do more research.

Senator HARKIN. $1 million a year?

Dr. FRAZIER. $1 million a year. Specifically for suicide.

Senator HARKIN. But there are other things——

Dr. FRAZIER. There are other moneys which have to do with depression and affective disorders.

Senator HARKIN. Are you doing research in the area of—what I understand is adolescent suicide may be contagious, one suicide triggers another—this sort of thing?

Dr. FRAZIER. Yes; we have collaborated with Dr. Mark Rosenberg of CDC, who, with Dr. Davidson there, has made the interviews of the various clusters of suicides. In Wind River, WY, in Plano, TX, Clearlake City, TX, in Houston, TX, and in Westchester County, NY, we have suicide clusters of 8, 9, or 10 adolescents. It usually starts with an outstanding person in a school, and then there is a kind of mimicry. There is a social contagion hypothesis about how suicides catch on. The teenagers don't necessarily know each other, they just learn about each other through the media. However, in Wind River, WY, they did know each other. Everybody was on the same reservation.

So we don't have a clear picture of what it is.

ADM BLOCK GRANT

Senator HARKIN. Mr. Trachtenberg, what will be the impact of the fiscal year 1986 sequestration under Gramm-Rudman-Hollings on State administration of the alcohol, drug abuse, and mental health block grants?

Mr. TRACHTENBERG. There will be a $21 million reduction in the Block Grant Program as a result of taking the required 4.3-percent reduction. Approximately 29 States will be held harmless, or in other words, will not go below the level that they received in the base year of fiscal year 1984. The remaining 28 States and territories will take a 4.3-percent or greater reduction.

Senator HARKIN. Why? Why not all 50 States?

Mr. TRACHTENBERG. That is a good question, and we know that Senator Proxmire has introduced legislation defining how the Gramm-Rudman reductions will be applied to the block grant. The block grant law currently provides that all States must be held harmless against receiving less than their 1984 award. If we applied the 4.3-percent reduction against these 29 States, each would fall below their 1984 award level, in violation of the hold harmless provision. There has to be a modification of the current law with regard to this provision.

It is ironic that those States who gained a more equitable award level in 1985 are now the ones hurt the most. However, our actions are based upon the advice of our general counsel.

ALZHEIMER'S DISEASE

Senator HARKIN. Dr. Frazier, please describe the National Institute of Mental Health's activities on Alzheimer's disease and how much will the Institute spend in 1987 and is it enough to pursue all of the opportunities available to research the causes and treatment of Alzheimer's disease.

Dr. FRAZIER. The actual obligations in 1985 were $11.3 million for all research on aging and that amount included $5.8 million for Alzheimer's disease. After the sequestering in 1986 it would be $12.149 million for all aging research, including $5.7 million for Alzheimer's disease. Both amounts are approximately the same in 1987.

Senator HARKIN. That's $12.1 million?

Dr. FRAZIER. $12.1 million for all research and $5.7 million just for Alzheimer's disease. Now, in addition to actual moneys being spent for aging and Alzheimer's, there are some researchers working in the basic neurosciences in the intramural and extramural programs. They are working on the cells of the brain, and thus give insight into the causes of Alzheimer's disease.

We are at the point of knowing that there are some special proteins present only in the brains of Alzheimer's victims. The Albert Einstein College of Medicine has identified a protein called ALZ-50. It may be recognized as a biological marker down the road to test, to make the diagnosis before autopsy. That would be interesting if it were so.

We also have other basic studies looking at memory. In our intramural program, Mortimer Miskin is studying two forms of memory, the memory of geographic space, where you are located in a particular area, and then the memory that is relative to form. For example, just looking at a face and recalling it. The two memory forms are in two different parts of the brain.

As we find out the areas where certain kinds of memory occur, then we also can find out, by simulating certain lesions, the resulting defect when that kind of memory is lost. That is what Alzheimer's is about basically. It is a memory loss over time in an individual.

We also are looking at the kind of depression that goes with Alzheimer's. A lot of people have both Alzheimer's and a depression on top of it. Heretofore, if they had Alzheimer's everybody simply assumed that we did not have any effective treatment. Now we know that the depression that occurs with Alzheimer's is treatable, usually by a monoamine oxidase inhibitor, and that relieves a lot of the disability that goes with the Alzheimer's. In addition, we have a whole group of people who have what is called pseudo-dementia, or false dementia. They look like Alzheimer's victims but they really have a basic depression. They are treatable, and they don't have the same future or the same course which Alzheimer's has.

Senator HARKIN. How do you avoid duplication with the Neurological Institute?

Dr. FRAZIER. Well, basic science is basic science wherever it is. Duplication has to do with the clinical area. In the clinical area there are not many people in the Neurological Institute who are going to look at the dementias with the psychosis that occurs in Alzheimer's. They recognize that doing research on people who are out of touch with reality and sometimes aggressive is the particular province of the National Institute of Mental Health.

So I think it is a matter of focus and the clinical side which is different.

Mr. TRACHTENBERG. There is one other fact I would like to add. That is that all grant applications are received at a central office at NIH, including those for NIMH and the other two Institutes. There are referral guidelines to determine which Institute would have the most interest in and relevancy to that particular application. There is an attempt to avoid duplicating research efforts.

ALCOHOLISM

Senator HARKIN. Let me ask a question about alcoholism. Mr. Archer, what evidence is there that alcoholism is hereditary? Is there solid evidence on that?

Mr. ARCHER. Yes; there is solid evidence now. First it started with epidemiological evidence showing a very strong predispositional relationship with heredity.

Senator HARKIN. Is it hereditary or just because the people who are alcoholics lived with parents who were alcoholics or something like that?

Mr. ARCHER. That is the first question we asked. Several of our researchers looked at the question of separated twins, where the twins were raised in different families, and we found there is an interaction between environment and biology, but biology is a very important portion of it. Adoption studies have also established that biology is a key to the transmission of alcoholism.

What we are looking at right now, and we have some very exciting research going on, is different genetic structure, what kinds of different brain proteins there are that can be identified. We have some early and exciting evidence on specific, unique brain protein which we think can serve as a marker of genetic susceptibility.

We are also looking at a number of other areas to try to, first of all, identify genetic markers and then determine if there is some way to influence that genetic predisposition. Research utilizing electrophysiological measures has shown that some sons of alcoholics have abnormal and unique brain patterns which are very similar to what alcoholics have. So we are beginning to target in on some of the basic mechanisms by which that pattern is being formed both in our animal and our human research.

Senator HARKIN. How much of your total budget is spent on research in this area, do you have any idea?

Mr. ARCHER. With these new findings, we have been advocating and encouraging new research. Research in this area has increased by approximately 20 percent since 1985, but I can give you the correct amount for the record if you like.

Senator HARKIN. OK, if you can get that for the record, that would be fine.

[The information follows:]

In 1985, $3.6 million, or approximately 7 percent of NIAAA's research funds were used for research in genetics and molecular biology. We anticipate that research in this area will increase in both 1986 and 1987.

RESEARCH AFFECTED BY BUDGET CUTS

Mr. ARCHER. In effect, it is a growing area, with the new findings we have.

Senator HARKIN. How will the 1987 budget cuts affect the research in this area?

Mr. ARCHER. It will not affect us substantially in the area of continuing grants. We will be looking at what cuts may be necessary in the funding of new grants, which is where our major impact would be in 1987. The reduction of dollar amount will be around 16 percent per new grant.

RESEARCH TRAINING

Senator HARKIN. Mr. Trachtenberg, you pointed out that your main responsibility is in the area of research. In the mid-1970's the research training budget was 11 percent of the total research funding. It is now 6 percent. Also, you are now training 882 trainees, while in the mid-1970's you were training twice that many. So how can we sustain a productive research program with these kinds of dramatic reductions?

Mr. TRACHTENBERG. There are two ways to look at this issue. One way is that we are getting a tremendous amount of excellent research. In fact, we are getting more good quality research than we can, in fact, support.

So one might argue: Aren't there too many researchers out there? My personal view is this is a matter of concern. The fact that this particular field of alcohol, drug, and mental health research grew significantly over the past 10 or 12 years is the result of the kind of investment that you described in the 1970's. It takes about 10 years to train a good researcher.

I am concerned that we are below the recommended levels of the National Academy of Sciences, and that we continue to drop further from these levels. I am also concerned about what impact this will have in terms of the future. So, on the one hand, while it could be argued that there is plenty of good research out there I have to tell you that I am concerned about the future.

Senator HARKIN. Is it OMB or the Alcohol, Drug Abuse, and Mental Health Administration?

Mr. TRACHTENBERG. In fiscal year 1986 we took the 4.3-percent reduction which reduced us by 40 trainees. In 1987 the OMB passback reduced the trainee level with the assumption that it was a proportionate reduction to reflect the reduction in the dollars attributed to the research.

Senator HARKIN. So OMB made these choices?

Mr. TRACHTENBERG. The 4.3 percent was just across each of the line items in 1986, and the 1987 research training reduction was below what we had requested as an agency.

Senator HARKIN. The staff has got a good point. Why didn't we restore it in 1987?

Mr. TRACHTENBERG. It was in our overall agency request but it was reduced.

Senator HARKIN. I think that was the point we were trying to get at. So you did ask for it to be restored, it was in your request to restore it.

Mr. TRACHTENBERG. Yes.

Senator HARKIN. And someone at OMB, someone who probably has no background in this area, made that decision.

Mr. TRACHTENBERG. I don't know, Senator.

Senator HARKIN. You don't know.

NATIONAL INSTITUTE OF MENTAL HEALTH

ST. ELIZABETHS HOSPITAL

STATEMENT OF DR. SHERVERT H. FRAZIER, DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH

ACCOMPANIED BY:

WILLIAM G. PRESCOTT, SUPERINTENDENT, ST. ELIZABETHS HOSPITAL
JAMES E. PITTMAN, ASSOCIATE DIRECTOR FOR ST. ELIZABETHS HOSPITAL TRANSITION

ST. ELIZABETH PATIENT DEATH

Senator HARKIN. Dr. Frazier, moving right along, I want to ask about St. Elizabeths, and I want to read a question that comes directly from Senator Weicker.

You can imagine my reaction when I learned that Mr. Emery Lee had died on January 18 of this year while in seclusion at St. Elizabeths Hospital. At my request—and as I said, this is Senator Weicker's question, so this is Senator Weicker's request—the District of Columbia Protection and Advocacy Agency explored the circumstances of Mr. Lee's death and the Health Care Financing Administration [HCFA] came to the hospital to investigate the death.

I also understand that the District delegate, Walter Fauntroy, is conducting an investigation into Mr. Lee's death. What are the findings of your hospital's investigation into Mr. Lee's death, and has HCFA reported to you on its findings?

Dr. FRAZIER. I, too, was very concerned and chagrined by the death of Mr. Emery Lee. It was a tragic occurrence. These reviews and investigations have been initiated, and we had our own internal reviews to look at whether the diagnosis, care, and treatment rendered were consistent with, or deviated from, accepted standards of practice. Specific focus was given to staffing patterns, number of persons who were present on the ward in the unit at the given time. Also, the division looked at it and the entire hospital staff looked at it. We didn't find any major changes in the staffing patterns.

There is an investigation by the D.C. medical examiner. We don't have that report yet. It generally takes a while to get the report from the autopsy. The D.C. homicide is also involved in an investigation.

HCFA came and they found some deficiencies in their hospital survey which was being conducted January 28 through 31 and those are being looked at. They are mainly in the recordkeeping area, internal

records about various events. That is being looked at carefully by us in response to the HCFA survey.

In additional, Congressman Fauntroy has declared his intent for hearings in early April. He has visited and his staff has visited, and they have secured the records and the charts and in the investigation have talked with the staff.

So we don't have the findings on these and we will obviously take very strong precautions, when we get these findings, to correct whatever has to be corrected.

Senator HARKIN. Did I hear you correctly that HCFA did report to you on some of its findings?

Dr. FRAZIER. They did report on some of the findings.

Senator HARKIN. Some of the findings. And you said they found some deficiencies?

Dr. FRAZIER. Patient record deficiencies. Dr. Prescott, the Superintendent is here.

Senator HARKIN. Dr. Prescott?

Dr. PRESCOTT. The HCFA investigation consisted of two parts. One had to do with an investigation into the death, and the rest of the HCFA evaluation was a regular HCFA survey of the hospital. The area in which we know we are going to need to make some changes is in the area of medical record documentation, but that was unrelated to the death.

HIRING FREEZE

Senator HARKIN. Dr. Frazier, I am concerned about your proposal to institute a hiring freeze at St. Elizabeths in fiscal year 1987. You estimate that it would save you 23 full-time equivalent positions. What impact will your proposal to reduce staff have on the quality of patient care at St. Elizabeths Hospital?

Dr. FRAZIER. It is not our intent, Senator Harkin, to reduce direct patient care staff. It is our intent to place a hiring freeze which will give us nonclinical care personnel savings, and we will also be responsible for carefully auditing the needs of every particular unit within the hospital and the staffing pattern for that unit.

But the hiring of nonpatient care staff would be frozen.

Senator HARKIN. Do you plan to replace the departing staff who handle the direct care of patients and who frequently experience burnout and may leave their jobs at a higher rate than those who work in administrative capacity?

Dr. FRAZIER. That is true. We don't plan the hiring freeze to cover nurses. So the nurse recruitment will continue throughout the period of the hiring freeze.

Senator HARKIN. Whose suggestion was the hiring freeze, yours or OMB's?

Dr. FRAZIER. Ours. It was our responsibility to develop the best way of accommodating the Gramm-Rudman reduction.

Mr. TRACHTENBERG. We are talking 1986 now, not 1987, Mr. Chairman. We had to take the 4.3-percent cut, and that is really I think what the big problem was in terms of staff level.

Senator HARKIN. Again I ask, will that be restored in fiscal year 1987?

Mr. TRACHTENBERG. Yes; it is.

PREPARED STATEMENT AND QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Senator Domenici wanted to be here but he is tied up with Budget Committee markup, and he has submitted questions for the record which he would like to have you respond to. Also, Mr. Trachtenberg, in the interest of time there are a lot of other questions we would like to submit to you for the record.

Mr. TRACHTENBERG. I would be pleased to respond to them.

Senator HARKIN. Mr. Trachtenberg, thank you very much.

[The information follows:]

Statement of Dr. Shervert H. Frazier

Thank you for the opportunity to present the budget request for Saint Elizabeths Hospital. The request for Fiscal Year 1987 will be the last request submitted to you on behalf of the hospital as an organizational part of the Federal Government. Pursuant to the provisions of Public Law 98-621, The Saint Elizabeths Hospital and District of Columbia Mental Health Services Act, management responsibility for the services now rendered by Saint Elizabeths Hospital will be transferred to the District of Columbia government on the first day of Fiscal Year 1988. Our Fiscal Year 1987 budget is designed to continue delivery of quality mental health services during the remainder of Federal stewardship. In addition to delivery of quality care, preparation for transfer of management responsibility is our most important goal for Fiscal Year 1987. During FY 1986, much has been accomplished to support the transfer of responsibility while maintaining quality of care. I would like to briefly summarize our accomplishments in support of the goals of this major legislation:

- A Preliminary System Implementation Plan has been completed by the Mayor's Mental Health Systems Reorganization Office and has been submitted to the District of Columbia City Council for review. This plan describes a comprehensive approach to the delivery of community based public mental health services to all residents of the District of Columbia. It contemplates reasonable reductions in the chronic long term adult inpatient population of Saint Elizabeths Hospital and substantial increases in program support in the areas of adult ambulatory care, child and adolescent services and forensic psychiatric services. Over 150 Saint Elizabeths Hospital staff participated in the development of this comprehensive plan.

- Preliminary draft staffing patterns have been developed by the District of Columbia for each of the service components described in the Preliminary System Implementation Plan. These staffing patterns have been distributed to all interested parties within the system for analysis and review.

- Detailed analyses of the physical facilities located on the campus of Saint Elizabeths Hospital have been completed. These analyses include a full physical plant audit mandated by the Act and the report of a consultant to the Mental Health Systems Reorganization Office. The framework for site planning and development of alternative strategies for physical plant utilization have now been laid.

- An audit of the financial statements of Saint Elizabeths Hospital has been completed pursuant to the requirements of the Act. The results of the audit were the issuance of a unqualified opinion that the financial statements fairly represent the financial position of the Hospital and that no material weaknesses were identified in the internal control practices of the Hospital.

- The Mayor has created a Reorganization Implementation Team and charged it with the responsibility for finalizing transition plans and implementing the System Implementation Plan. This team, made up of high ranking officials of the District of Columbia Department of Human Services, Saint Elizabeths Hospital, and the Department of Health and Human Services has already begun the process of transition which will allow uninterrupted delivery of quality services during this important transition period.

The budget request submitted to you has been prepared on the assumption that programmatic activities will be maintained at current levels during FY 1987.

Impact of Gramm-Rudman Legislation

However, consideration of the FY 1987 budget request necessarily requires analysis of the impact of the Budget Reduction and Deficit Control Act of 1985. Under this legislation, the Hospital will have approximately $3.7 million of its FY 1986 operating budget sequestered. As a result, the Hospital will achieve savings by imposing a hiring freeze for the remainder of the fiscal year which will bring its total staffing from approximately 3,385 persons to a target end of year workforce of 3,305. This represents a current-year reduction of 23 full-time equivalents, and will save approximately $1.3 million. In addition, reductions of approximately 8 percent in contract services, supplies, and equipment will save $1.8 million. Remaining reductions of $0.6 million in spending authority will be offset by increased reimbursements in areas not subject to Gramm-Rudman sequestration. The FY 1987 budget request assumes maintenance of the current operating level. The Gramm-Rudman legislation will not divert the Hospital from accomplishing its basic treatment mission for the remainder of FY 1986.

Fiscal Year 1987 Goals and Objectives

The Hospital's major focus during the remainder of FY 1986 and throughout FY 1987 will be preparation for a smooth transfer of treatment responsibilities to the District government consistent with the Preliminary System Implementation Plan. We do not intend to wait until October 1, 1987, to implement the major functional reorganization necessary to accomplish the District's new service delivery plan. During this period, we hope to accomplish the following objectives:

- Functional reorganization of Hospital inpatient programs to achieve alignment with the System Implementation Plan.

- Transfer of outpatient treatment responsibility from Hospital-based programs to existing community mental health centers, with appropriate reassignment of clinical staff to these centers.

- Completion of analysis of physical plant requirements to assure consistency with the District's physical plant utilization plan and redirection of unobligated facilities funds to final renovations.

- Completion of all necessary changes to the Preliminary System Implementation Plan consistent with the timetable contained in the legislation.

- Finalization of program staffing patterns preparatory to the transfer of employees to District government management on October 1, 1987.

Budget Request

The total 1987 budget request for the Hospital assumes spending authority of $136,754,000, representing a net increase of $7,630,000 over FY 1986 after Gramm-Rudman sequestration. This amount includes $7,530,000 to maintain an operating level comparable to that of the original appropriation, and $100,000 to conduct an audit of accrued annual leave balances required by the transfer legislation.

The budget includes a Federal Appropriation of $36,353,000 and reimbursements totaling $100,401,000.00. The reimbursements include a projection of $76,798,000 in payments by the District of Columbia

government, including the D.C. share of Medicaid reimbursements. The Hospital's projection of the District government payment represents a 22% increase over the FY 1986 level of $62,970,00.

Mr. Chairman, I will be pleased to answer any questions which you or members of the committee may have.

Biography of Dr. Shervert H. Frazier

Director
National Institute of Mental Health
Alcohol, Drug Abuse, and Mental Health Administration
U.S. Department of Health and Human Services

Shervert H. Frazier, M.D., assumed the directorship of the National Institute of Mental Health (NIMH) on December 4, 1984. NIMH, a component of the Department of Health and Human Services' Alcohol, Drug Abuse, and Mental Health Administration, is the world's largest mental health research support program, with an estimated 1985 operating budget of $283 million.

Dr. Frazier came to NIMH from Harvard Medical School, where he was Professor of Psychiatry and Psychiatrist in Chief at the school's affiliated McLean Hospital in Belmont, Massachusetts. His career previously encompassed a rich array of experiences in clinical practice, academic and public administration, and professional affairs.

A native of Louisiana, Dr. Frazier received his undergraduate and medical degrees from the University of Illinois. After serving as a medical officer with the U.S. Navy from 1944 to 1946, he established a private practice of medicine in southern Illinois. In 1951, he moved to the renowned Mayo Clinic in Rochester, Minnesota, where he accepted a fellowship in internal medicine and, subsequently, psychiatry. He moved to New York for the first time, in 1958. There, he engaged in research at the New York State Psychiatric Institute, in clinical duties at the Presbyterian Hospital of New York, and in teaching at Columbia University, College of Physicians and Surgeons.

Only four years later, Dr. Frazier was recruited to direct what is now the Texas Research Institute of Mental Sciences in Houston. Over the next few years he served also as Psychiatrist in Chief at Ben Taub General Hospital in Houston, Professor and Chairman of the Department of Psychiatry at Baylor University, consultant psychiatrist to the Veterans Administration Hospital in Houston, and Commissioner of Mental Health and Mental Retardation for the State of Texas.

Dr. Frazier returned to New York in 1968; there, he served as Deputy Director of the New York State Psychiatric Institute and assumed a variety of senior faculty positions in the Department of Psychiatry, Columbia University. In 1972, he moved to Boston where he remained twelve years in the positions noted previously.

Experienced in psychiatric and neurobiologic research, certified in psychoanalysis, and trained in the diverse administrative spheres of academia, hospital management, and state government, Dr. Frazier brings an impressive array of skills to the direction of the national mental health program. At a time when the Federal program is emphasizing the conduct and support of research and rechannelling its former direct involvement in service delivery and professional training into an emergent national

leadership role, his broad perspective on issues confronting the mental health field will be invaluable.

Dr. Frazier has been actively involved in the professional affairs of mental health and medicine broadly for more than three decades. He has and continues to hold numerous leadership positions in the field: past Chair of the American Medical Association's Residency Review Committee on Psychiatry and Neurology; past president of both the American College of Psychiatrists and the Association for Research in Nervous and Mental Disease; President of the VI World Congress of Psychiatry; and, Secretary of the American Psychiatric Association. A hallmark of his contributions to each of these bodies has been his insistence on the need for more effective communication among specialties and disciplines and between the professional community and the public. Toward those ends, he served for more than seven years as chairman of psychiatry's Joint Commission on Public Affairs.

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

REQUEST FROM THE PUBLIC HEALTH SERVICE

Question. Mr. Trachtenberg, what did you, as the Acting Director of the Alcohol, Drug Abuse, and Mental Health Administration, request of the Public Health Service for your 1987 budget?

Answer. ADAMHA submitted to PHS a 1987 budget request of $1,081,709,000. The amount requested was sufficient to meet all commitments as well as provide a 4.2% inflationary increase over the 1986 President's budget level. Also included was $84.5 million for the following enhancements:

- o A increase of 150 new and competing grants, for a total of 650, and funding of all new, competing, and continuation awards at full Council-recommended levels ($26.7 million);

- o Two new centers in NIMH for schizophrenia and childhood disorders; for NIDA, one cooperative agreement for the development of a center for epidemiology research; for NIAAA, funding to expand epidemiological research and develop a National Data System ($11.6 million);

- o Demonstration grants which, because of their size, could not be accomodated within the existing research grant budget ($15.0 million);

- o Funding to provide full utilization of the Addiction Research Center 32 bed facility; expansion of Nuclear Magnetic Resonance (NMR) and molecular genetics technology; and replacement of obsolete, existing equipment ($12.8 million);

- o An increase of 249 research trainees, for a total of 1,247 trainees ($6.6 million);

- o Funding to expand research dissemination and prevention efforts ($2.8 million);

- o Funding for additional repairs and renovations to ADAMHA's intramural facilities ($4.7 million);

- o Funding for additional repairs and improvements to the facilities of St. Elizabeths Hospital ($4.3 million).

As the 1987 request was submitted to PHS prior to the 1986 Conference action, the amount requested does not reflect adjustments required as a result of the disallowance of multiyear funding nor the increase to 550 new and competing grants in 1986.

AIDS RESEARCH ACCOMPLISHMENTS

Question. In FY 1986 ADAMHA received $12 million for research and technical assistance related to AIDS. Please bring us up to date on what has been accomplished.

Answer. Research on AIDS is supported by both the National Institute of Mental Health (NIMH) and the National Institute on Drug Abuse (NIDA). NIMH is continuing to support research focused on the psychiatric, neuropsychiatric, bio-behavioral, psychoimmunoligical and psychosocial aspects of AIDS. Studies focused on the relationship between psychological conditions and immune function, changes in high risk behavior patterns, the correlation of behavior changes with immunological status, and psychological reactions to the HTLV-III blood test are under way. NIMH is placing a priority on psychoimmunological research. Investigators have hypothesized that persons with a antibody to HTLV-III will show increased incidence of AIDS and ARC with increased stress and depression, and decreased incidence with increased social support and coping skills.

NIMH research has provided support for studies focusing on the changing patterns of intimacy in the gay community. Those men who are in primary relationships engage in less high risk sexual activity both with their partner and with others and appear to be healthier psychologically and physically. Researchers indicate that although current knowledge of AIDS and awareness of "safe sex" guidelines about risk factors were uniformly high, such information was not consistently used by gay men as a basis to behavior change. This objective may require efforts targeted to specific components of the gay community, notably individuals who have been in the gay lifestyle for more than 9 years.

Research is also currently under way to assess the mental health status of persons with AIDS and AIDS-Related Complex (ARC). The most striking finding is that the ARC group shows higher levels of psychological distress and is significantly in need of more psychosocial intervention than had been previously understood. Further analyses will determine whether persons with ARC remain so distressed over time, and how diagnosis of AIDS in some of those persons influences these measures.

NIDA has been actively participating in an array of AIDS

programmatic activities. The forthcoming "co-factors" conference scheduled for May 29 and 30, 1986 is but one example. NIDA joined forces with NIMH to bring together a highly select group of scientists to present their ongoing research on the behavioral and neuroscience factors which influence the course of the HTLV-III infection. Their research and counsel will help us to direct the course of future research initiatives.

Approximately $1.6 million of the AIDS funds have been used to initiate programs in prevention, public information, and technology transfer. These efforts include a series of workshops and technical assistance efforts for State drug abuse authorities, developing video tapes, training manuals and media campaigns, and establishing an 800 treatment referral line. We have also developed a repository of findings and materials about AIDS and IV drug use and have initiated monthly mailings to State drug authorities of the new materials.

The Addiction Research Center in Baltimore, studies to detect the presence of HTLV-III virus in human serum samples are underway as are studies to assess the effects of abused drugs on the immune function. In addition, plans have been completed, and renovations and equipment ordered for an HTLV-III screening laboratory to handle 2000 screenings per year in cooperation with extramurally-funded epidemiological studies.

Ongoing extramural studies include the following: a study of the variations of seropositivity of IV drug users by geographical, racial, and sexual parameters; assessment of needle-using and sexual practices of parenteral drug users to determine prevalence of HTLV-III infection and to develop a health promotion model; and study on the seroprevalence of HTLV-III among IV drug users.

AIDS RESEARCH

Question. I have read that the number of AIDS cases in intravenous users continues to increase. Is there any indication that public education efforts regarding the use of sterile needles has had any positive impact among intravenous drug users?

Answer. The increased awareness that HTLV-III diseases are transmitted by needle sharing has begun to change needle use patterns among intravenous drug users. Intravenous drug users in New York City are beginning to buy more needles and syringes on the street. This has been documented by an increase in the street price of the needles and syringes. In New Jersey, street indigenous workers (recovered intravenous drug users) are providing educational material directly to drug users who have not yet decided to enter treatment. While it is difficult to determine if the average number of individuals who share needles has decreased in the "shooting galleries" (the common places where drug users buy their drugs and rent drug administering paraphernalia), it is clear from recently completed surveys that almost one-half of all admissions in drug abuse treatment programs in New Jersey are indicating that one of the reasons for their seeking treatment at this point in time is their fear of contracting AIDS.

Question. Recent reports indicate that dementia is being seen in some AIDS victims. What can you tell us about this?

Answer. An investigator at Sloan Kettering has recognized that afflicted patients frequently suffer a variety of central nervous systems (CNS) complications. While some of these are well recognized opportunistic conditions, much more common is a progressive encephalopathy referred to as AIDS dementia, which has not previously been described in other immunosuppressed patients. In adults this encephalopathy characteristically manifests as a subacute dementia accompanied by motor dysfunction. In its early stages, AIDS dementia is marked by a general slowing in thinking, memory, and motor functions. Changes in personality may also be present, along with apathy, withdrawal, and loss of interest in socialization. Organic psychosis also occurs at the earliest stages, although less frequently than the less dramatic symptoms. Moderate to severe global cognitive dysfunctions may appear within three months of the appearance of the first symptoms. The hallmarks at this late stage are global cognitive impairment and psychomotor slowing. Only rudimentary intellectual and social functioning remains. Patients typically die of intercurrent infection.

Question. What kind of research initiatives are being undertaken?

Answer. NIMH has taken the lead in issuing with NIDA and NIAAA a joint Request for Application to stimulate AIDS research. Currently, more than 30 proposals have been received. It is anticipated that at least 5-10 new grants will be awarded as a result of this activity. One cycle of reviews has been conducted, with 4 projects recommended for funding consideration. A special review will be held in the late spring or early summer to permit funding before the end of FY 1986.

NIMH and NIDA also plan to make awards for two or three AIDS research centers to provide a structure for bringing research and dissemination activities into a coordinated unit. The centers are conceptualized as facilitating the rapid dissemination of new knowledge into clinical practice, and to the research and training communities. Centers may request up to $500,000 per year over a five year period. Currently, 10 expressions of intent to submit center grant applications have been received.

NIMH is planning to collaborate with the NIH, NIDA, NIAAA, CDC, and FDA in sponsoring a conference related to AIDS Co-Factors. The conference is scheduled for April 7-9, 1986.

NIMH is also planning to sponsor a conference with NIDA and NIAAA concerned with the neuroscience and behavioral science aspects of AIDS. This conference is scheduled for May 29-30, 1986. NIMH is also participating in the NIH Consensus Conference on the HTLV-III Blood Test in July 1986.

NIMH plans to bring together the investigators currently supported who are developing inventories which measure psychosocial and mental health aspects of AIDS. A workshop to synthesize finding and to identify areas in need of future research is planned for August 1986.

Question. Will you be able to do this research within your $12 million AIDS budget?

Answer. At this point it appears that research, training, and research dissemination, specifically prevention and public education activities, might be done within the $12 million AIDS budget. There has been a strong, high quality response to the research announcements, especially from nationally recognized medical facilities and researchers who are actively involved in AIDS research endeavors.

EDUCATIONAL SUPPORT FOR HEALTH CARE WORKERS

Question. What kind of educational programs does ADAMHA conduct for health care providers on the treatment of patients with AIDS?

Answer. Educational programs related to AIDS are supported by both the National Institute of Mental Health (NIMH) and the National Institute on Drug Abuse (NIDA). With regard to NIMH, the institute has issued a request for contract proposals for "Training for health care providers to address AIDS". The contractor will be required to provide comprehensive AIDS programs to address the special mental health educational needs of research groups. These groups include medical and other health care students, primary care residents, psychiatry residents, nurses, social workers, counselors, psychologists, and staff physicians. Also included will be programs of training for health care providers currently providing, or administratively responsible for, health care to AIDS patients in hospitals, private offices, clinics, community mental health centers, and community based organizations.

The centerpiece of NIMH AIDS information activities is a pamphlet designed to sensitize health care workers to the psychological needs of people with AIDS and others with HTLV-III infection. Scheduled for publication in Spring, 1986, Coping With AIDS: Psychological and Social Considerations in Helping People with HTLV-III Infection provides enough information for health workers to recognize mental health needs and problems of both their patients and themselves. It also recommends how to cope with these problems.

NIMH is also currently developing the following: a pamphlet to help friends, families, and others close to people with AIDS cope with the mental health needs of the patient and themselves; a report on the findings of NIMH-supported investigators studying the psychosocial aspects of AIDS; a brochure that would help non-physician health care workers recognize the signs and symptoms of neurological damage in AIDS or ARC patients; and a monograph on psychoimmunology research and its implications for AIDS.

With regard to NIDA, the institute is completing the development of a series of manuals designed to clarify program practices relating to facility management and to counseling activities in relationship to HTLV-III testing; working with the HTLV-III client; teaching prevention strategies to the intravenous (IV) drug user; counseling with the HTLV-III client's family, etc. Manuals will be developed

separately for criminal justice and health care personnel working with intravenous drug users. Making use of those manuals, the institute is organizing a total of approximately 45 workshops, 30 for drug abuse treatment personnel and 15 for criminal justice and health care providers, to deal with issues of program management and counseling the IV drug user.

In addition to the above, NIDA will be developing video cassettes designed to illustrate individual and family counseling strategies with HTLV-III clients as well as providing assistance in the development of mutual support groups for HTLV-III clients. Technical assistance in terms of on-site guidance and direction will also be provided to drug abuse treatment personnel.

RESEARCH FUNDING LEVELS

Question. I believe that the quality of your research program is excellent, evidenced by peer review panels recommended funding for 65% of the grant applications submitted for review. Given the FY 1987 budget proposals, what percentage of these approved grants will be funded?

Answer. We expect to fund 29% of the applications approved.

Question. What message will this send to the young scientist starting a research career?

Answer. Although the competition for research grants in the ADM fields has become increasingly stiff, research funding is still available to individuals who submit high quality research applications. Approximately 250 new grants will be funded in FY 1987 and in the past about half of the new grants have been made to investigators receiving their first ADAMHA project grant. The young scientist starting a research career undoubtedly is already keenly aware that he/she will need to develop very high quality research proposals in order to succeed in the current research environment.

CLINICAL TRAINING PHASEOUT

Question. For the fifth consecutive year, the Administration is proposing the elimination of the Clinical Training Program.

What information do you have to indicate that shortages of trained clinical personnel do not exist?

Answer. There is no nationwide data available upon which one could make a conclusive national judgment regarding mental health personnel shortages. However, there does exist a range of anecdotal and local community and State data which indicate a maldistribution of personnel. In general, mental health personnel are adequately available in metropolitan areas for the provision of services to less seriously disturbed individuals who have adequate

third-party coverage. Conversely, there are significant shortages in non-affluent, rural areas, and inner cities where large segments of the population (usually minority) do not have adequate third party coverage. Mental Health personnel prepared to provide community-based services to the more seriously disturbed children and adolescents, chronically mentally ill, and the aged (e.g., psychosocial rehabilitation personnel) are in very short supply in most communities regardless of size or location. The recent NIMH clinical training initiatives have been specifically targeted to addressing these shortages.

Question. What other sources of support exist in the absence of Federal support for the training of clinical personnel?

Answer. Other possible sources of support for graduate education include teaching or research fellowships or assistantships, university or private scholarships, internships or residences funded by the agency or hospital, outside employment, support from parents or spouse, or, of course, educational loans.

Question. What evidence do you have to support the conclusion that the clinical training program will continue to function productively without Federal support?

Answer. With the exception of social work, we have seen no drop in enrollment for graduate training in the four core mental health disciplines since NIMH support for clinical training began to decrease in 1981. The number of individuals being trained seems more than sufficient to fill available jobs.

GRANT COSTS

Question. At what average cost to you expect to fund research grants in FY 1987 and how does this compare to FY 1986?

Answer. The average funded new and competing grant in 1987 will be $132,321. This level represents a 1.7% increase in direct costs over the 1986 average.

Question. Will these grants be funded at Council recommended levels?

Answer. All grants in FY 1987, new and competing, as well as continuations will be reduced from Council recommended levels. We estimate the reduction for new and competing grants at 13% and continuations at 4%.

COST OF GRANTS

Question. Specifically how does Council judge at what level a grant should be funded and how does that usually compare to the amount requested by the applicant?

Answer. Council recommendations usually follow the

recommendations of the Initial Review Groups (IRGs) which consider the appropriateness of the requested budget in the context of their evaluation of the scientific and technical merit of an application. The IRGs look at the overall budget and specific budget categories to determine if the estimates are reasonable in terms of the work which the investigator proposed to be carried out and the IRG's recommendation as to whether the whole project or only some parts of it should be funded. Typically a project which receives an excellent priority score is recommended for a higher percentage of requested funds than other projects because the IRG also makes a recommendation for support of the entire proposed project. Nonetheless, in all cases, the IRG closely scrutinizes proposed expenses to be sure they are reasonable and well justified.

Question. How do you explain the rapid rise in costs and in your professional judgment what can be done to control these escalating costs?

Answer. A number of factors appear to be contributing to increasing average costs of grants. We have a work group looking into these factors and considering what actions might be appropriate in response to these increases. One of the factors we have noted to date is the higher cost of doing research in high priority areas of national need (e.g., prevention and epidemiology) and in areas of rapidly expanding technology and scientific opportunity (e.g, the neurosciences). ADAMHA has been increasing its level of effort in these areas in recent years, and this is part of the explanation for the increase in average costs. The work group is still in the process of analyzing the information which they have collected. We anticipate that a report will be available around late April, 1986.

EFFECT OF SEQUESTERING ON RESEARCH GRANTS

Question. The loss of funds due to FY 1986 sequestering has not reduced the number of grant awards. How much has each grant been reduced, and what effect will these reductions have on the research involved?

Answer. Due to sequestration, new grants will be reduced by 13% while competing grants and continuations will be reduced minimally, i.e., 1% or less. This approach was taken to preserve the integrity of on-going projects. It will however require a reduction in scope for new projects.

ECONOMIC COSTS OF ALCOHOLISM

Question. What are the economic costs of alcoholism to this nation in terms of morbidity, mortality and lost productivity?

Answer. A 1984 study on the economic costs to society of alcohol abuse, drug abuse, and mental illness found that the costs to the nation of alcohol abuse in 1983 were $116.7 billion. Lost productivity ($65.6 billion) and lost employment ($5.3 billion) account for more than half of this amount. Treatment accounts for $14.9 billion, and mortality accounts for $18.2 billion of the total costs. The balance of $12.7 billion is for other related costs, including the costs of alcohol-related motor vehicle crashes and alcohol-related crime.

ALCOHOL USE AMONG YOUTH

Question. To what extent have public education efforts been effective in reducing alcohol use among teenagers?

Answer. A promising trend has emerged over the past few years in terms of alcohol use among youth. A nationwide study conducted by the University of Michigan Institute for Social Research, which collected sample data of all senior high students in public and private high schools in the United States, has indicated that between 1975 and 1984, the annual prevalence rate of alcohol use among high school seniors fell from 88 percent to 86 percent; monthly prevalence from 72 percent to 67 percent; and daily prevalence from 6.9 percent to 4.8 percent. A promising trend has also been reported in terms of reduction of alcohol-related traffic fatalities among 15- to 19-year old residents of one State which implemented a chemical-free graduation celebration during the 1979-80 school year. While it is not possible to attribute these downward trends to any single prevention approach or strategy, public education efforts have played a substantial role. Further, research findings suggest that prevention strategies that combine a variety of approaches are more effective than any single approach.

SYNTHETIC NARCOTICS

Question. What research does the National Institute on Drug Abuse support on the production and uses of synthetic narcotics? What have you learned about the effect of such synthetic drugs, particularly the long-term effects of their use?

Answer. Research into MPTP, and synthetic analogs of controlled substances in general, has been initiated. Investigations of the nature and extent of MPTP use in California and now other parts of the nation have been conducted by the Centers for Disease Control and the National Institute on Drug Abuse. In January, 1985, CDC and NIDA began to interview and locate persons who may have been exposed to MPPP and MPTP. The study found that since 1982 approximately 50 persons have reported the use of a substance which produced symptoms similar to those reported by known users of MPPP/MPTP. Preliminary results from the study, conducted at the request of the State of California, suggest that over 400 persons may have been exposed to MPTP in California. During the field investigation, 173 persons reported that they had experienced symptoms similar to those reported by known users of the drug. To date, 83 of these persons received a complete evaluation, consisting of a lifetime drug history, a report of the signs and symptoms indicative of the early stages of the Parkinsonian syndrome and a brief neurologic examination. Ongoing field studies of the extent of MPTP use and its severe adverse health consequences are currently being undertaken by these agencies to determine if the MPTP-induced Parkinsonian syndrome has spread to other locations in the United States.

At the same time, NIDA continues to support research projects seeking to understand basic mechanisms of action in synthetic analogs of controlled substances. In order to provide synthetic

analogs of controlled substances to researchers for this purpose, NIDA maintains the ability to synthesize compounds and distribute them to research laboratories for chemical and pharmacologic evaluation. Although PCP itself is now controlled in Schedule I of the Controlled Substance Act, over 35 analogs of PCP have been synthesized by NIDA. Recently, NIDA has produced large quantities of MDMA in order to study its abuse liability in animal models. In June, 1984, the production of 3-methylfentanyl was carried out by NIDA to provide the Drug Enforcement Administration with an authentic sample of this recently controlled substance. Several other analogs are also being prepared.

Data on the extent of abuse and the adverse health consequences of drugs are needed to schedule substances under the CSA. The synthetic analogs of controlled substances, however, are extremely difficult to track through existing drug abuse data systems operated by NIDA. Not only are the substances so closely related chemically to a parent compound thus creating identification problems, but as in the case of the fentanyl analogs, toxic doses are often so small they are easily overlooked by routine laboratory analysis. As a result, data collected from hospital emergency rooms and medical examiners across the nation and reported to NIDA's Drug Abuse Warning Network do not provide a valid measure of the synthetic analogs of controlled substances problem in this country. We do have other means of gathering these data, however, including special epidemiologic studies, such as the NIDA-CDC collaborative project mentioned earlier, and NIDA's Community Epidemiology Work Group (CEWG). In its most recent semi-annual meeting held in June, 1985, CEWG members reported that the fentanyl compounds continue to be a severe problem in southern California. In San Diego, 24 fentanyl related deaths have been reported since mid-1982, with 10 deaths occurring during 1984 and four more deaths so far this year. Indications that fentanyl analogs are available in other areas of the country, including New York and Atlanta, were also noted. Several preliminary reports from the CEWG also suggest that meperidine analogs may have become available in other parts of the country outside California.

Efforts of NIDA to further understand the health implications of the synthetic analogs of controlled substances will continue to focus on epidemiologic studies, research investigations, synthesis and distribution of compounds, and knowledge dissemination activities.

Question. How is the National Institute on Drug Abuse dealing with synthetic narcotic drugs in its prevention programs? What kinds of information are you providing to educate the public through the use of mass media and our young people through our educational system about these dangerous new substances?

Answer. Our activities have not been limited to research. The National Institute on Drug Abuse notified the drug abuse treatment and prevention community nationwide of the dangers of MPTP. Together with the National Institute on Mental Health (NIMH), NIDA prepared a report on MPTP for publication in the Morbidity and Mortality Weekly Report (MMWR), the Centers for Disease Control publication which reaches a national audience of physicians. This report served as

the basis for an article later published in the Journal of the American Association which reaches an even wider audience. The July, 1985 issue of NIDA's "Clinical Research Notes" contains an article summarizing recent findings about the possible neurotoxicity of MDMA.

In 1985, NIDA participated in a Public Health Service sponsored symposium on MPTP in Bethesda, Maryland during which scientists from several countries presented findings on the toxicity, clinical pathology, and epidemiology of MPTP.

The Institute has developed a coordinated schools drug abuse prevention program which it is now in the process of implementing. In association with that program, we will take several "social innoculation" or peer resistance studies that have been undertaken to date and, by selecting the significant parts of the strategies studied and found effective, organize programs specific to the functioning of elementary school students, middle school students and high school students. Specifically, we will be organizing peer resistance games and activities at the elementary school level, strategies that lend increased self-esteem and prestige within the peer community at the middle school level, and the development of classrooom educational materials to be incorporated in middle and high school health and/or science curricula at the middle and high school levels. Thus, we intend to have a three-pronged attack on drug taking by adolescents and pre-adolescents who will be targeted through the schools. At the same time, we are continuing to promote our highly successful "Just Say No" media campaign which has now been adopted by the National Broadcasting Company, working in conjunction with NIDA, to encourage young people to reject drugs. Similarly, the activity has been adopted by the National Collegiate Athletic Association (NCAA) as well as professional sports industries.

In specific relation to synthetic narcotic drugs, NIDA will continue to monitor the nature and extent of the use of those substances through its existing epidemiologic programs and continue, as it has over the past year, to publish materials for the prevention and treatment communities describing drug phenomenon in terms of both the dangers posed and the responses available.

PREVENTION RESEARCH

Question. What kinds of epidemiological and prevention research is the National Institute on Drug Abuse supporting on the relationship between drug use and AIDS.

Answer. The initial focus of NIDA's AIDS research program is to clarify the extent to which intravenous (IV) drug users are infected with the human T-cell lymphotropic virus, type III (HTLV-III), and to determine risk factors for exposure to HTLV-III. Such epidemiological research has been initiated in New York City and San Francisco. Research is also being conducted in New Jersey, Washington, D.C., and New Orleans.

Another important area of research is to develop and test interventions to prevent the spread of the infection. In order to

assist in the identification of promising intervention approaches, ethnographic research is being conducted in New York City to determine the extent to which IV drug users are informed and concerned about the potential spread of AIDS and the extent to which these concerns are influencing behavior. Researchers in San Francisco are also developing and evaluating a health promotion model to reduce high-risk behaviors among IV drug users.

NIDA is currently in the process of expanding its AIDS research program. Two grants program announcements have been issued to solicit quality research in priority areas, and the first group of applications are currently in the review process. In addition, a contract to monitor the seroprevalence of HTLV-III infection in selected cities across the United States is being developed. This monitoring system will permit assessment of the spread of the infection on an ongoing basis.

SCHIZOPHRENIA RESEARCH

Question. We have just received your report on current initiatives being pursued in research into schizophrenia. What progress can you report in the research for schizophrenia?

Answer. Among the many projects being carried out with NIMH support, several recent imaging studies have been particularly interesting. Dr. Nancy Andreasen at the University of Iowa, using magnetic resonance imaging (MRI), has recently reported that the frontal region of the brain is smaller in schizophrenic patients than in controls. This is particularly important since the frontal lobe may mediate many of the negative (or deficit) symptoms of schizophrenia which are less responsive to antipsychotic drug treatment.

Other evidence of a frontal lobe dysfunction includes that recently reported by Dr. Raquel Gur of the University of Pennsylvania and Dr. Monte Buschsbaum of the University of California at Irvine. Using a technique called positron emission tomography (or PET) scanning, several researchers have determined that schizophrenic patients show a relative "hypofrontality" or lower metabolic activity in the frontal region of the brain. A number of imaging studies are now under way to clarify the specificity of this finding, medication effects, clinical-biological correlations, relation of imaging results to course and outcome, etc.

Research in the treatment of schizophrenia is predicated on the use of antipsychotic medication which still remains the bedrock of care for these patients. Two avenues of work are proving increasingly fruitful. One represents the synthesis of many years of investigation on the efficacy of neuroleptic drugs. This research has shown the value of medication in the shortterm treatment of acute symptoms, the crucial role of medication in prevention of relapse and the possibility of obtaining these benefits with lower than typical doses of medication. This work has recently led to studies combining lower than normal dosages with a highly specific form of family therapy. The family treatment emphasizes development of problem solving skills.

The NIMH initiated a collaborative clinical trial in 1985 to

provide a definitive study of such reduced dosage strategies and family treatment. This study and other large scale clinical trials are looking to investigate treatments that will be applicable to the broad range of patients with schizophrenia.

A second significant approach in treatment research, in schizophrenia is seeking to identify homogeneous subgroups of patients defined by specific symptom clusters such as anxiety or depression that persist even after treatment with antipsychotic medication. These specific symptoms are then treated with medication--antidepressants or anxiolytics. Results from a study of antidepressants by Dr. Samuel Siris at Mt. Sinai Medical Center are highly promising and the expansion of this strategy to other symptom clusters will represent a significant research approach in the next several years.

Question. What would be the cost of a comprehensive 5-to-10 year program to improve the prevention and treatment of schizophrenic disorders?

Answer. An accurate cost estimate for a comprehensive program to improve our understanding of etiology (the first step in any prevention consideration) and treatment development would require an extensive effort over an extended period of time. As important as the area of prevention of schizophrenia is, most scientists do not feel that we are at a point where a major initiative in this area would be productive. We need to know more about the development and course of schizophrenia, but until we have additional knowledge about the potential etiologies of this illness, it would be premature to attempt to implement specific "prevention" activities at this time.

RESPONSE TO IOM STUDY ON MENTAL HEALTH

Question. The Institute of Medicine released a report in 1984 that stated "The amount of research on the disorders...within the ADAMHA domain is much too low, given their enormous costs to society". The study goes on to say that support for ADAMHA research and research training should undergo an orderly increase over the next five years.

What is your reaction to the Institute of Medicine study and what steps has your agency taken to respond to that study?

Answer. We have circulated this report widely within the agency and among the scientific community. We agree with the reports conclusions that the health consequences and economic costs of ADM disorders are immense and that there are many areas of exciting research opportunities which are not being fully exploited given current funding levels. We also are aware of the current national fiscal situation and the hard choices which have to be made about scarce resources. We have attempted to inform a wide variety of publics --including, e.g., the scientific community at large, foundations, state and local government officials, organizations representing the interests of persons suffering from ADM disorders -- of the costs of these disorders and the opportunities for

advancement through expanded research efforts. It is our hope that this information dissemination will enhance the basis for informed decision making about resource allocations in various parts of the public and private sectors.

We also have circulated the report among our advisory groups. Recommendations in the IOM report concerning areas of scientific opportunity have been considered in developing program plans for areas of increased emphasis.

RESPONSE TO IOM STUDY ON MENTAL ILLNESS

Question. Your budget request for mental health research for FY 1987 is $195 million. In your professional judgment, what should the budget request be if you could be fully responsive to the Institute of Medicine study?

Answer. The IOM Report recommends that NIMH research effort should be funded at a minimum level of $300 million 1983 constant dollars. Corrected only for domestic inflation this would be equivalent to approximately $347 million for FY 1987.

IOM STUDY AND RESEARCH TRAINING

Question. The Institute of Medicine study also states, "NIMH now supports fewer research trainees than at any other time since 1963...despite clear needs of researchers in a number of areas...."

Why are you proposing to reduce support for research training by almost $2 million in the face of this clear shortage?

Answer. While we may agree that there is always benefit in training more researchers, we also note that currently we have a considerable number of applications from very competent researchers that we are unable to fund. The payline of the agency is the best it has ever been and we are funding only 43% of approved applications. Given this situation, the funding of new trainees has a secondary priority which we had difficulty supporting in time of tight federal budgets.

BLOCK GRANT SERVICES FOR IMMIGRANTS AND REFUGEES

Question. What information do you have on State activities under the Alcohol, Drug Abuse, and Mental Health Block Grant to ensure that the mental health problems of immigrants and refugees are addressed?

Answer. The provision of mental health services specifically to immigrants and refugees is not a requirement of the Alcohol, Drug Abuse, and Mental Health Services (ADMS) Block Grant legislation. Neither is specific information concerning immigrants and refugees required in a State's application for Block Grant funds nor in its annual report. However, information gathered during our compliance reviews indicates that some States with immigrant and refugee problems are utilizing the ADMS Block Grant funds as well as

other sources of funds in their attempts to deal with these problem areas.

ALCOHOL AND PRENATAL CARE

Question. What types of research does the National Institute on Alcohol Abuse and Alcoholism do on the fetus, particularly in the area of fetal alcohol syndrome?

Answer. NIAAA has supported research on alcohol and pregnancy for over 10 years, since the initial recognition that heavy alcohol use in pregnancy could result in a unique cluster of birth anomalies and mental impairment termed the fetal alcohol syndrome (FAS). The results of this research led to the issuance of a Surgeon General's Advisory on this subject in 1981. A number of important health issues pertaining to alcohol use in pregnancy, and its impact on fetal outcome and infant health, remain unresolved and the NIAAA is continuing to support research to address these questions. The experimental approaches involve human epidemiologic investigation and animal studies to assess the effects of alcohol on the fetus, and on subsequent behavioral and neurologic functioning. Questions under study include (a) the identification of specific gestational periods of risk for alcohol-derived fetal injury; (b) correlation of specific birth defects (e.g., organ anomalies, growth impairment, brain impairment) with the time of gestation at which alcohol exposure occurs; (c) characterization of the nature of the brain injury and mental impairment which can result from alcohol misuse; (d) identification of the lower dose thresholds of alcohol necessary for major injury, and for the more subtle neurologic impairments which may affect eventual school performance and other aspects of behavioral and cognitive functioning in life; (e) identification of the biochemical or pharmacological mechanism by which alcohol induces such fetal injury, with the aim of developing interventions and therapies to reduce the probability of injury when alcohol has been misused in pregnancy.

STABILIZATION OF RESEARCH GRANTS

Question. Your budget proposes to place a target for the total number of research grants supported by your three research institutes. Why is this proposal necessary since limitation on the number of new and competing grants entering the system also stabilizes the total number of awards?

Answer. The number of new and competing awards entering the system does not completely stabilize the total number of awards because of the varying length of awards. By targeting the total level at a reasonable average cost, we are able to project a consistent, predictable budget for health research.

RESEARCH PRIORITIES

Question. Please provide this Committee by April 1 a complete list, by Institute, of both intra and extramural research priorities. This list must include all research priorities or initiatives that are judged by your advisory councils as important

to the future of mental health, alcohol and drug research without regard to budget levels.

Answer. The research priorities for both extramural and intramural, by Institute are listed below:

NIMH:

In NIMH, the highest research priorities for its extramural and intramural programs are basic research on the brain and behavior, schizophrenia, disorders of children and adolescents, mental disorders of the aging, and behavioral medicine including AIDS.

Within these broad categories, NIMH will pursue more specific basic and clinical research priorities:

Basic Brain: the process of co-transmission, the development of drug probes for investigating neuropeptides, the identification and functioning of post-receptor mechanisms, the measurement of messenger RNAs and their product proteins, the examination of brain plasticity and neurogenesis, the creation of standardized approaches to functional brain imaging analysis, the neural mechanisms of memory, the structure of genes, the transplantation of genetic materials, the discovery of new brain substances, the neurobiology and neuropharmacology of social behaviors in primates, circadian rhythms in depression and manic-depressive illness, the relationship between serotonin and aggression and the impact of stress on body systems, particularly the immune system.

Basic Behavior: the development of emotions, the link between memory and emotional states, the exploration of cognitive processes, and the emergence of psychopathology in family systems.

Schizophrenia: the genetic predisposition to schizophrenia, the heterogeneity of schizophrenia, the nature of the core symptoms of schizophrenia and the treatment of schizophrenia.

Disorders of Children and Adolescents: the risk factors associated with disorders of children and adolescents, the multiple determinants of adolescent suicide, the diagnosis and assessment of attention deficit disorder and conduct disorder, the development of effective psychotherapies for childhood and adolescent disorders.

Mental Disorders of Aging: the treatment and management of Alzheimer's disease with a special focus on family issues, depression among the elderly, the emergence of late onset schizophrenia, the major psychoses, and the mental health consequences of physical illness in the elderly.

Behavioral Medicine: the role of the immune system in major mental disorders; the relationship between lifestyle and disease including AIDS; the psychosocial needs of AIDS victims; the relationship between AIDS and cognitive impairments; the neurological, psychological and physiological factors involved in anorexia nervosa and bulimia; the biomedical and behavioral aspects of obesity, and the chronogiological rhythms involved in sleep disorders.

NIDA:

In NIDA, the highest priorities for research are in the areas of cocaine,the biological bases of vulnerability to drug abuse, the treatment of drug abusers, and the so-called "designer drugs."

The dramatic increase in the use of cocaine over the last several years surprised both the general public and many people in the health field. Although cocaine has been used in this country for a considerable time, until recently its use was restricted to relatively small numbers of people. As a result, comparatively little research has been conducted on cocaine and how to treat cocaine abusers. As the use of cocaine has become more widespread in recent years, our research program on cocaine has expanded, and the continued expansion of research in this area remains one of our highest priorities. In particular, research to determine how cocaine affects the brain, the dangers associated with various forms of cocaine use, and the development of effective treatment regimens for cocaine users will be expanded.

Another area that will be given high priority involves research to determine the biological and behavioral bases of vulnerability to drug abuse. One of the mysteries associated with drug abuse is why some individuals or groups appear relatively more or less vulnerable to drug abuse. We know, for example, that while relatively large numbers of people try drugs, only a comparatively small number go on to regular use, and of these, an even smaller number proceed to compulsive use. If we knew why some individuals seem able to resist the attractions of drug use while others seem to be overpowered by it, we could greatly improve our prevention and treatment efforts. Research conducted over the last several years indicates that both biological and environmental factors may be factors in vulnerability to drug abuse and many of these leads will be followed. For example, recent research in the alcohol field has shown that some forms of alcoholism have a genetic base. Investigations will be made to determine if there is a similar genetic base to vulnerability to drug abuse. Research will also be conducted to explore what appears to be a link between aggressive and impulsive behavior and subsequent drug abuse. Other factors, such as nutrition which influences the turnover of certain neurotransmitters, will also be explored.

A third area which will receive special attention is research on the treatment of drug use. While much of our research program is directed at ways of preventing drug abuse, there is an obvious need for more effective ways of treating drug abusers. This need is made greater by the recent trends toward non-opiate drug use and the growing numbers of adolescents seeking treatment. Most of our past research on drug abuse treatment focused on the treatment of opiate abusers. As greater numbers of non-opiate users have come into treatment, it has become clear that many of the techniques and methodologies used in the treatment of opiate users are not suitable for non-opiate users or for adolescents. We are, therefore, planning to increase our research into the development of more effective treatment regimens for non-opiate users and for

adolescents. One area that will receive special emphasis will be research on treatment programs for cocaine.

Finally, high priority will be given to research on synthetic analogs of controlled substances, the so-called "designer drugs." Although legislation is pending that would automatically bring these drugs under the jurisdiction of the Controlled Substances Act, it appears certain that clandestine laboratories will continue to produce these compounds. Because of extreme danger of many of these compounds, NIDA will continue to work closely with the Drug Enforcement Administration by producing standard preparations of these substances for research and conducting toxicology and abuse liability tests on them.

NIAAA:

In NIAAA, the highest research priorities are:

- Treatment research, including studies to improve diagnostic instruments; and patient placement research to determine the relative efficacy of different therapies, the appropriateness of inpatient versus outpatient program settings for different types of patients, the optimal length of stay in residential facilities, and the ideal mix of services ranging from detoxification to aftercare.

- Research in genetics and molecular biology to learn the physiological and biochemical bases of genetic vulnerability to alcoholism and to identify genetic markers of susceptibility.

- Research in the neurosciences, including research into the mechanisms by which alcohol produces adaptive responses in nerve cells; studies on neurotransmitters known to be present in specific brain areas that are affected by alcohol; and research into the similarities between alcohol-induced cellular changes and those associated with aging.

- Prevention research to learn what interventions and policy changes can prevent alcohol-related problems and how these approaches can most effectively be combined into comprehensive prevention strategies.

- Research into alcohol's effects on the immune system and the role of alcohol in the development of AIDS and other infectious diseases.

- Application of molecular genetics techniques to studies of alcoholism and alcohol-derived disease states.

- Development and testing of improved pharmacologic tools for the treatment of alcoholism.

- Application of nuclear magnetic resonance (NMR) technologies for determining the mechanisms producing tolerance and physical dependence and for developing novel approaches for the diagnosis and evaluation of alcohol-induced organ damage through noninvasive (nonsurgical) procedures.

Question. Please indicate which priorities would be pursued at the FY 1987 budget request level and then at FY 1987 pre-sequestering current services level.

Answer. Because all of the above listed areas are of high priority, all of them will be pursued to the extent made possible by available resources.

STUDY SECTIONS/PRIORITY SCORES

Question. I understand that the priority scores on grants have undergone signifcant grade inflation. Are the study sections becoming more lenient or are we actually seeing more sophisticated applications?

Answer. We believe it is probably a combination of factors contributing to the trend toward higher priority scores. While IRGs are probably to some degree reacting to the budgetary situation and concommitant decreasing paylines, we also firmly believe that the quality of science is improving and that we are seeing more sophisticated applications. For example, new imaging technologies have made possible the study of relationships between brain, behavior and illness which we were not able in the past to measure in such a direct way. Also, techniques for large scale community base diagnostic interviewing have been developed and standardized and these permit much more reliable epidemiologic research.

INDIRECT COSTS

Question. Are indirect costs a major item in the overall cost increase of research grants?

Answer. Indirect costs are one item contributing to the overall increase in project grants costs, but they do not appear to be the greatest contributing factor. We are currently involved in an indepth study of factors contributing to the increase in costs, and will have more information about this in the near future.

Question. In your professional judgment, is the change in administrative costs mandated by OMB realistic?

Answer. It remains to be seen whether this policy will result in a long term reduction in overall costs to the Federal Government of supporting research. Institutions may eventually increase their requests for direct costs in certain categories as a result of this policy. However, all direct costs will continue to be subject to close professional scrutiny through the peer review process to determine the reasonability of the costs requested.

Question. Will the reduction in indirect cost reimbursement have serious long-term affects on the Universities' ability to support biomedical research?

Answer. Since the reduction will affect only the administrative categories and not the categories supporting the research infrastructure such as libraries, utilities, and computer support, we believe research will not be damaged in the long run.

BLOCK GRANTS

Question. You have indicated that ADAMHA has, as required monitored and conducted compliance reviews of Block Grant recipients. Have the States continued to monitor services at appropriate levels.

Answer. Alcohol, Drug Abuse, and Mental Health Services (ADMS) Block Grant recipients, as required by law, have been subjected to periodic compliance reviews. To date, we have completed on-site compliance reviews in 40 states. The information gained during these compliance reviews indicates that the States have monitored the services funded by the ADMS Block Grant at an appropriate level. The legislation requires a yearly audit of all sub-recipients of funds. In addition, most States have an independent evaluation process whereby they monitor sub-recipient performance.

Question. How much of State activity in the areas of alcohol and drug abuse is being paid for by the Block Grant funds?

Answer. The Alcohol, Drug Abuse, and Mental Health Services (ADMS) Block Grant State Compliance Review Program does not require States to report what percentage of their State activities are paid for by ADMS Block Grant funds. However, a report prepared for the National Institute on Alcohol Abuse and Alcoholism and the National Institute on Drug Abuse entitled, "State Resources and Services for Alcohol and Drug Abuse Problems - Fiscal Year 1984," indicates that the ADMS Block Grant accounts for approximately 19% of the total financial allocations by States for alcohol and drug abuse services.

Question. How have the States implemented the new required Block Grant activities, i.e., 3 percent set aside for women in drug abuse and 10 percent for severely disturbed children?

Answer. Information gathered from the Alcohol, Drug Abuse, and Mental Health Services ADMS Block Grant State Compliance Review Program has indicated that the States are implementing the required ADMS Block Grant set asides. ADAMHA is required to report to Congress specifically on the States' utilization of the set aside funds. This report is being prepared and will be submitted to Congress by the required date.

Questions. Have you identified any serious problems in the use of Block Grant funds? If so, what are these problems and how have you dealt with them?

Answer. ADAMHA has completed approximately 40 on-site State compliance reviews concerning compliance with the Alcohol, Drug Abuse, and Mental Health Services (ADMS) Block Grant legislation requirements. Approximately 35 percent of the States receiving ADMS Block Grant funds have, at the time of the review, been found in non-compliance with one or more of the legislatively

mandated requirements of the law. Between the time of the compliance review and the submission of the final report to the Governor, ADAMHA has been able to work with the individual States to assist them in meeting compliance with the mandated requirements of the law in all but one case. That particular State has provided documentation indicating that appropriate action is be taken to reach compliance. ADAMHA will be verifying that in the near future.

In addition to the non-compliance findings and follow-up actions taken by ADAMHA, a great deal of ADMS Block Grant State Compliance Review time and effort is directed towards improving the individual States' overall administration of its Block Grant program. For those States which have undergone compliance reviews, ADAMHA has made technical assistance recommendations in over 83 percent of the compliance review draft reports. The average compliance review report made 4-6 recommendations regarding an individual State's administration of its ADMS Block Grant Program. The usual State response to the draft report indicates almost total acceptance of the recommendations and, in most cases, includes implementation plans in response to the recommendations.

Question. Have any States developed successful new initiatives utilizing Block Grant funds?

Answer. Many States have indicated to ADAMHA that the flexibility provided by Alcohol, Drug Abuse, and Mental Health Services (ADMS) Block Grant funding has allowed them to develop successful new approaches and initiatives to the delivery of ADM services. Many States have used the ADMS Block Grant funds as the source of revenue for innovative programs. They have been able to use the funds to develop new approaches to traditional ADM Services problem areas and as the source of revenue to support demonstration programs within their States.

Many States, as part of their annual report, are describing the new and innovative ways which they have utilized Block Grant funds. An analysis of these reports in greater detail is being planned in the future. This information will be utilized in developing and distributing data on exemplary programs to the States.

Question. How are the successful innovations communicated to other States wishing to improve their Services?

Answer. The Alcohol, Drug Abuse, and Mental Health Services (ADMS) Block Grant legislation provides for the provision of technical assistance by ADAMHA. Two Block Grant technical assistance workshops have been sponsored by ADAMHA - one in March, 1985 and the second in October, 1985. These workshops have provided an opportunity for ADAMHA and State staff to come together to meet and share the problems and exemplary activities associated with the ADMS Block Grant legislation.

ADAMHA is currently planning a third ADMS Block Grant Technical Assistance Workshop to describe and disseminate

exemplary activities in the area of substance abuse prevention supported with Block Grant funding. Successful innovative programs developed by the individual States will be documented in detail and disseminated to all recipients of the ADMS Block Grant funds.

CLINICAL TRAINING

Question. I have just received the report on the mental health training programs.

How many predoctoral and postdoctoral trainees with payback requirements have you supported for each of the past four years in each of the mental health disciplines?

Answer. The following table show the number of stipends awarded in each discipline which incur a payback obligation.

Stipends Awarded for Payback Support, FY 1982-1985
by Discipline and Level of Award (Predoctoral or Postdoctoral)

	Psychiatry		Psychology		Social Work		Nursing		Total	
	Post		Pre	Post	Pre	Post	Pre	Post	Pre	Post
1982	36		678	28	572	9	593	-	1,843	73
1983	53		303	21	255	-	152	-	710	74
1984	45		346	25	304	-	174	2	824	72
1985	36		392	30	345	-	203	-	940	66
Total	170		1,719	104	1,476	9	1,122	2	4,317	285

Question. What is the percentage of each discipline's support that reflects payback funding?

Answer. In general, the amount of a grant devoted to trainee rather than teaching costs reflects the amount which may be called payback funding. In FY 1985 this percentage of the grant for each of the disciplines was as follows: nursing, 61 percent; psychiatry, 10 percent; psychology, 85 percent; social work, 78 percent.

VOCATIONAL REHABILITATION TRAINING

Question. What can you tell us about the joint program with the Rehabilitation Services Administration that is training mental health professionals and vocational rehabilitation counselors in the community care of the chronically mentally ill?

Answer. This program provides joint in-service training for mental health professionals and vocational rehabilitation counselors who work with chronically mentally ill adults in the community. Late in 1985, NIMH provided $257,000 of its Clinical Training funds for the support of two projects: one with the

Rehabilitation and Crippled Children's Unit of the Alabama Department of Education, and the other with the Human Services Training and Research Council, Inc. of Charlottesville, Virginia. RSA funds support 4 additional projects, for a total of 6 projects in this area. NIMH also assists RSA in program monitoring and the provision of technical assistance to grantees.

DEPRESSION

Question. During the FY 1986 budget hearings, Dr. Macdonald described research being conducted on a skin test to identify individuals that may have a greater predisposition to depression. Please bring us up-to-date on this research.

Answer. Research on receptors in peripheral cells that are similar to brain receptors continues in an attempt to identify abnormalities in psychiatric illness shared between brain cells and other cells in the body. Although the initial results of this work, published in 1984, suggested that certain receptors on skin cells would identify persons with genetic vulnerability to manic-depressive illness, further studies in the laboratory originating these findings, and in other laboratories, have not corroborated this prediction. Similar research on adrenergic receptors on lymphocytes (a form of white blood cells) appears more promising at this time.

Question. Is there any work being done to try and identify the gene that may be causing this problem?

Answer. Advances in molecular genetics now allow the human genome to be scanned using linkage markers; a systematic scan of the entire complement of human genes is now theoretically possible. Efforts supported by the ADAMHA institutes (as well as NIH institutes) are identifying new gene markers and are expected to make scanning of the entire genome a reality within a decade.

There appear to be several independently inherited vulnerabilities to ADM disorders, including schizophrenia, manic-depressive and related mood disorders, Alzheimer's disease, and alcoholism. Using newly developed molecular genetic techniques, DNA is being extracted from immortalized white blood cells of members of extended families in which these psychiatric illnesses occur. After appropriate laboratory procedures, it is possible to determine if any of the scanning gene probes identify a chromosomal region linked to the disorder found in a particular family. Proteins are collected from these cells and used for the same purpose, using high-resolution electrophoretic techniques that allow numerous markers to be studied in a single procedure.

Gene mapping of ADM disorders appears to be a high-payoff area of research at this time, and many investigators are initiating studies and collecting appropriate specimens from large families with the illnesses.

NUCLEAR MAGNETIC RESONANCE FACILITY

Question. I understand that you have been working with the National Institutes of Health toward the development of a centralized Nuclear Magnetic Resonance Facility (NMR).

What are the total costs of this facility, and what is the level of ADAMHA's involvement?

Answer. The total estimated cost of the Nuclear Magnetic Resonance Facility is $6.3 million. This figure covers start up costs, building and equipment. In FY 1986, ADAMHA's contribution will be $575,000 ($500,000 and $75,000 from NIMH and NIAAA, respectively). The NIAAA will continue to contribute $75,000 per year through FY 1990. In addition to these funds, the alcohol intramural program will be housing a high resolution spectrometer in the NMR facility, which will be available to other users of the NMR program at the NIH. The cost for this spectrometer, of $425,000, will also be funded by the alcohol intramural program.

Question. I assume you are funding this program using intramural funds. If this is correct, how does this affect your research efforts?

Answer. Both the NIMH and NIAAA will use intramural funds for the Nuclear Magnetic Resonance Facility. This incudes NIAAA's share of costs for the centralized facility as well as the purchase of a specialized spectrometer to be house in the facility. The availability of this technology will open the way for the program as a whole to address some very important questions at a level of sophistication and detail not previously possible. In view of the substantial gains that are possible by the application of NMR technology to the clinical problems of mental health and alcohol abuse, this area is considered a high priority by both the Institutes and will be supported despite the need for an overall intramural programmatic decrease reflected in the FY 1987 budget. This will be achieved in FY 1987 by the refocusing of a number of ongoing intramural projects in relevant scientific areas, so as to begin to exploit the availability of NMR technology.

BLOCK GRANT FUNDING FOR THE HOMELESS

Question. The number of homeless Americans has risen dramatically; it is estimated that as many as 30 percent of these people show signs of mental illness. Do your data show how States are using Alcohol, Drug Abuse and Mental Health Block Grant funds to deal with the problems of the homeless mentally ill?

Answer. The Alcohol, Drug Abuse and Mental Health Services (ADMS) Block Grant legislation does not require the States to provide services specifically to the homeless mentally ill. Therefore, there exists no direct reporting mechanism for information on this group. However, to the extent that the block grant allows the provision of a range of comprehensive community mental health services, the expectation is that States will utilize a portion of these funds to extend services to those in the homeless population who also suffer from mental illness.

AIDS

Question. What kinds of technical assistance is NIDA providing to health care providers regarding the needs of drug users

who are infected with the AIDS virus? Describe the activities NIDA is carrying out to expand its dissemination of information regarding drug use and AIDS?

Answer. NIDA is completing the development of a series of manuals designed to clarify program practices with regard to facility management and to counseling activities in relationship to HTLV-III testing, working with the HTLV-III client, teaching prevention strategies to the intravenous drug user, counseling with the HTLV-III client's family, etc. Manuals will be developed separately for criminal justice and health care personnel working with intravenous drug users. Making use of those manuals, the Institute is organizing a total of approximately 45 workshops, 30 for drug abuse treatment personnel and 15 for criminal justice and health care providers, to deal with issues of program management and counseling the IV drug user.

In addition to the above NIDA will be developing video cassettes designed to illustrate individual and family counseling strategies with HTLV-III clients as well as providing assistance in the development of mutual support groups for HTLV-III clients. Technical assistance in terms of on-site guidance and direction will also be provided to drug abuse treatment personnel.

DRUG ABUSE PROBLEMS OF WOMEN

Question. What research is being supported under the authority of Public Law 98-509 on the special drug abuse problems of women?

Answer. The National Institute on Drug Abuse has focused on the particular problems and needs of drug-abusing women and their offspring. Each Division in NIDA has continuing efforts under way dealing with drug abuse and women and has been planning for new activities in this regard. Specifically, we have geared our data systems to look at gender as a variable, and we plan to do retrospective and current reports on race and gender differentials on our survey data. We also plan to supplement existing grants to include women in studies on drug abuse and violence (victims and perpetrators).

We are soliciting applied research grants to study gender differences on smoking and addiction; PCP and cocaine gender differences; and prevention and intervention in drug use, misuse and abuse by women. In addition, we are publishing findings from review papers and roundtable discussions resulting from a technical review on teenage single parents and drug abuse, as well as a monograph based on the May 1985 Technical Review, Women and Drugs: A New Era of Research.

Some of our long-standing grant projects have to do with the effects of various drugs in women, the methods of detoxifying women who are addicted to heroin, and the outcome of women and men treated in traditional drug modalities. Our own intramural research program at the Addiction Research Center is planning to admit, on a pilot basis, two or more women who will remain in residence with other subjects in a study of marijuana's effects on biological and immune systems.

In the technology transfer arena, NIDA has developed a bibliography on women and drug abuse and a mailing list of programs interested in this area, and has been working on an Alcohol, Drug Abuse, and Mental Health Directory on Treatment and Prevention Resources for Women. In addition, we will continue to conduct women and drug abuse workshops at national conferences to transmit research findings on treatment and prevention to State and local policymakers and service providers. We are also working on implementing recommendations from a Public Health Service task force on women and health.

DRUG ABUSE PREVENTION

Question. What research projects are being supported under the authority of Public Law 98-509 for the development and demonstration of methods for the prevention of drug abuse?

Answer. NIDA continues to support demonstrations in the area of prevention research which will add to the growing body of knowledge local prevention programs can draw upon to meet specific community needs. Typical of the demonstration projects NIDA supports are those testing the effectiveness of a media and school-based approach designed to discourage children from initiating tobacco use; testing a primary prevention model of cognitive skill building with adolescents and their parents designed to help children prepare for more independent decision making and life planning; and testing the effects of message style and format on drug abuse prevention literature and prevention media campaigns.

ALCOHOLISM AMONG NATIVE HAWAIIANS

Question. How is NIAAA responding to this Committee's directive to give special attention to the needs and problems of Native Hawaiians regarding alcoholism and alcohol abuse?

Answer. The NIAAA is continuing to seek applications for research projects on issues which can lead to improved prevention and treatment approaches to be used with ethnic populations, including native Hawaiians. The Institute continues to offer consultation to Hawaiian investigators who wish to apply for research funding. One application has been submitted recently and is scheduled for review by the Initial Review Group in June.

Last September the Institute supported a minority research conference to address the epidemiology of alcohol use and abuse among ethnic and racial minorities in the United States. The proceedings of this conference will be available later this spring and will include recommendations for future research directions.

A recent grant award, through the Minority Scholar Program, will provide support for a scholar who will provide direction and expertise in identifying research needs, designing and developing research projects, and conducting research on alcohol use and abuse by Americans of Pacific Islander/Asian heritage. Staff from the Institute will be working with this grantee to maximize research in this important area.

ALCOHOLIC PATIENT PLACEMENT RESEARCH

Question. How has your agency responded to this Committee's directive to aggressively pursue patient placement research with the objective of determining the levels of care appropriate for various types of alcoholics, the costs of such care, and benefits derived from providing a wider spectrum of treatment modalities?

Answer. The NIAAA has taken a number of important actions to pursue patient placement research. These actions range from support of efforts to develop validated screening instruments for early detection of harmful alcohol consumption, to development of clinical guidelines for determining necessities for various treatments, to support of multi-site assessments of inpatient and outpatient treatment regimens. Last July, we issued an in-depth, highly focused grant program announcement on the topic of matching clients to treatment. Applications have already been received and we are continuing to widely disseminate this announcement. To further encourage sound research in this area, the NIAAA has published and disseminated a variety of materials on alcoholism treatment issues to assist researchers in developing high quality projects.

The NIAAA has convened two subpanels of outside experts to evaluate various aspects of patient placement research. One of these is a clinical group; the other is a research group. The clinical subpanel has begun to establish clinical guidelines which should be followed in determining which patients need inpatient detoxification, and which may need inpatient treatment as opposed to treatment in other settings. The research subpanel has begun to formulate recommendations as to which diagnostic and measuring instruments should be used to assist both clinicians and researchers in advancing efficient patient placement. Both subpanels will also be working to develop recommendations as to the best treatment outcome measures. These recommendations will clearly advance research by allowing greater standardization in treatment research.

The NIAAA, in conjunction with NIDA and ADAMHA, are working with the American Psychiatric Association (APA) in reformulating the diagnostic criteria for alcohol and drug dependence. These guidelines will be included in "The Diagnostic Statistical Manual" (DSM IIIR), to be published by the APA in October 1986.

Recently funded research related to patient placement includes a large scale multi-site treatment assessment study comparing inpatient and outpatient treatment regimens among persons in the workforce. Given this project's randomized design, it is expected to make an important contribution to our knowledge base. Another study, in collaboration with the World Health Organization, has developed a standardized cross-culturally validated screening instrument for early detection of persons with potentially harmful alcohol consumption and is testing the treatment efficacy of brief, inexpensive treatment interventions. There is some preliminary indication that brief treatment interventions can be as efficacious as more expensive and longer term treatments for persons with uncomplicated alcoholism.

PSYCHOTHERAPY

Question. What research is NIMH supporting in the area of psychotherapy, including the evaluation of various treatment approaches?

Answer. NIMH is currently supporting psychosocial and behavioral treatment research on affective disorders (e.g., depression, anxiety), disorders of children and adolescents, the elderly, and schizophrenia. The treatment approaches include various forms of cognitive, behavioral, and psychodynamic interventions delivered individually, in a group, or in a family setting. Our grant portfolio includes studies on both the efficacy of these treatment approaches and the processes and mechanisms by which they bring about change. About half of the projects in the portfolio are comparing more than one approach. The NIMH Treatment of Depression Collaborative Research Program is an example of comparative treatment studies to evaluate interpersonal therapy, cognitive therapy, imipramine (antidepressant drug) plus clinical management, and placebo plus clinical management. A number of other projects we support involve evaluation methods with development and validation of psychometric measures to assess treatment.

With increasing evidence of the general effectiveness of a number of psychotherapeutic approaches, many researchers have shifted their focus to the efficacy of specific approaches for specific disorders. With regard to schizophrenia, for example, NIMH supports a research project (Hogarty and Anderson, University of Pittsburgh) on evaluation of environmental-personal treatment in the prevention of relapse of schizophrenia. In current clinical practice, approximately 70 percent of schizophrenic patients will relapse within 2 years of discharge from hospitalization. The best controlled clinical trials of medication treatment still yield a 40 percent relapse rate. Clearly, some other form of treatment is necessary to reduce this high relapse rate. Hogarty and Anderson's study has demonstrated an extremely important finding. They were able to demonstrate that reducing the overstimulating and demanding elements of the recovery environment leads to a prevention of relapse. Further, from this work they were able to demonstrate a delay in relapse up to one year from a combined social skills/family psychoeducational approach even if the environment did not change.

RURAL PREVENTION

Question. What research does NIMH support on demonstrations of the effectiveness of comprehensive prevention programs in rural settings?

Answer. NIMH addresses mental health needs of populations in rural areas through activities under its Community Support Program (CSP). The CSP is a national effort to promote the development of support systems for the long-term mentally ill, and to improve the quality and appropriateness of services and opportunities for this population. The NIMH Division of Biometry and Applied Sciences (DBAS) has completed a study examining the development of Community Support Programs in 10 rural and 10 urban States as well as six local areas in each of the 20 States. In addition, DBAS has

initiated a study of the relationship between service costs and client outcome among chronically mentally ill adults in one rural and one urban State.

On April 4-5 in Chicago, NIMH and the Council of State Governments will sponsor a national policy forum on mental health aspects of the current rural crisis: the emotional and behavioral consequences of personal stress for farmers and rural Americans. Research indicates the problem extends beyond the acute and sensational events to long term, severe impact on families, especially children and adolescents. The national forum will review the extent of the problem, the impact on communities, and the programs that have helped ease this situation. Its goal is to foster collaboration among policymakers and community leaders and to develop recommendations for future action.

NURSING REPRESENTATION

Question. I note that NIMH has one nurse on its Advisory Board but the concern still exists that your agency does not give sufficient priority to appointing professional nurses to its advisory committees and that research and training applications from schools of nursing are not receiving appropriate levels of funding?

Answer. The National Advisory Mental Health Council is responsible for providing policy advice to the Director of NIMH and is constituted by both professional representatives of various mental health related disciplines and lay members who represent the public interest. We consider ourselves fortunate that we have been able to recruit a professional nurse to serve on this Council. Most of the other advisory committees in the NIMH are charged with peer review activities and their membership is selected on the basis of the range of specialties required to provide expert review of applications initiated in the field. The lack of representation of professional nurses is a reflection of the relative lack of applications requiring review of professional nurses. In cases where the work load does not justify the appointment of an individual representing a particular discipline or specialty, the standard practice in our initial review groups is to invite reviewers on an ad hoc basis until such time as representation on a standing committee is warranted and a vacancy becomes available. Since committee members usually serve staggered terms of four years, such vacancies arise on a regular basis. Institute staff encourage applications from all disciplines relevant to our mission, but funding levels for a particular specialty are a function of the applications approved at fundable priority score levels and their relation to Insitute priority areas.

RESEARCH TRAINING

Question. How does the current ADAMHA research trainee level compare to the recommendations of the National Academy of Sciences?

Answer. Based on extrapolations developed jointly by ADAMHA and NIH, the 1986 ADAMHA research trainee level is approximately 56 percent of the level recommended by the National Academy of Sciences.

Question. How do you defend this discrepancy?

Answer. The recommendations of the National Academy of Sciences are based on an ideal situation and do not take into account actual budget levels. Our current request reflects what the Administration believes we can reasonably afford, given current budget constraints.

Question. Is this consistent with a comparison of the NIH level to the NAS recommendations?

Answer. The National Institutes of Health (NIH) research trainee level is about 90% of the level recommended by the National Academy of Sciences.

Question. Has the level been more in line historically?

Answer. The NIH research trainee level has been about the same although the ADAMHA level has been closer to the level recommended by the NAS. The gap between the number of trainees recommended by the NAS and the number of trainees supported by ADAMHA continues to increase, in light of decreasing budget levels.

Question. What is ADAMHA doing in response to the 1985 NAS report which recommends restoring predoctoral support to the 1981 level and gradually increasing predoctoral support?

Answer. The 1985 NAS report makes a number of recommendations regarding the number of trainees which should be supported in the Basic Biomedical Sciences, Behavioral Sciences, Clinical Sciences, Health Services Research, and Nursing Research. These multiple recommendations assume higher levels of funding than what is currently available and relate to the Public Health Service overall. The NAS report recommends, for both the Basic Biomedical and the Behavioral Sciences, restoring predoctoral support to the 1981 level and gradually increasing postdoctoral support. The agency is striving for a research training program that supports a balance of predoctoral and postdoctoral trainees and encourages training for ADM research careers in the biological, behavioral, and clinical sciences, and in epidemiology. We have tried, within this context, to be reasonably consistent with the NAS recommendations and specific program needs in developing our FY 1986-1987 NRSA funding policy. ADAMHA plans to continue to provide approximately 50 percent of the traineeships/fellowships at the postdoctoral level and to make awards consistent with the research priorities of the Institutes.

Question. Why does the training program receive such low priority for funding when it directly relates to your investigator-initiated grant program, a high priority?

Answer. Funding for research training is directly related to our investigator-initiated grants program. As such, the level of funding requested is consistent with the Administration's intent to support a total of 1400 research project grants in 1987.

Question. We understand that the effect of the new authorization legislation will be to set aside 1% of your research training funds for other programs. Is this true? Where will they go?

Answer. The Health Research Extension Act, P.L. 99-158, included a new directive which provides that, beginning in 1986, one-half of one percent of the research training appropriation will be setaside to fund research trainees in primary medical care while an additional one-half of one percent shall be available for trainees in health services research. This funding will be used to establish research training programs in these two areas.

MINORITY FELLOWSHIP SUPPORT

Question. What is the current level of support for the Minority Fellowship Program?

Answer. With the proposed rescission of funds for clinical training, the Minority Fellowship Program will support 4 projects and 69 trainees, at a total dollar level of $690,000 in fiscal year 1986.

MENTAL HEALTH NEEDS IN JAILS

Question. What has NIMH done over the past year in developing training programs to address the pressing mental health needs of those incarcerated in our nation's jails?

Answer. Last year, the Center for State Human Resource Development at NIMH launched the Local Mental Health and Jails Initiative. Through this Initiative, support may be provided to demonstration projects designed to improve mental health services in local jails through the development and implementation of training programs, that are undertaken collaboratively by jail and local mental health services personnel.

Of the nineteen States that applied under this Initiative, seven were approved and funded with up to $20,000 (viz., Hawaii, Maine, Maryland, Mississippi, New York, West Virginia, and Wisconsin) for a total expenditure of $135,000. Although program objectives for these grants differed among States as a result of urban/rural environment, racial and ethnic mix, and organizational resources and constraints, program emphasis to meet the following goals applied to all grantees:

1. to develop and implement curriculum to teach jailers how to recognize symptoms of mental illness;

2. to provide crisis intervention services to mentally ill offenders; and

3. to develop formal interagency agreements between local mental health providers and jails so that mental health services are available to mentally ill offenders.

MENTAL HEALTH NEEDS OF WOMEN

Question. What projects are you supporting that are targeted on the mental health needs of women?

Answer. In Fiscal Year 1985 NIMH supported 142 research grants which targeted women's mental health needs. The total

expenditure for these research projects was almost $17 million. These projects included such diverse research areas as depression, stress, family issues, mental health problems of victims, gender identity and roles, eating disorders, and mental health syndromes related to the reproductive and menstrual cycle.

The Office of the Associate Director for Special Populations is NIMH's designated entity to provide leadership and coordination in developing and fostering programs and administrative policies which would promote the mental health concerns of women. Public Law 98-509 (1984 Amendments) expanded the scope of the Associate Director of Minority Concerns to include women as a priority population and changed the title of that Office to reflect that expansion. A Special Assistant for Women's Mental Health recently was added to that Office and, with the assistance of an NIMH Women's Mental Health Liaison Committee, is developing an array of activities designed to address gaps in research and service delivery related to women's mental health. The Office also is coordinating NIMH's implementation of the relevant recommendations of PHS' Task Force on Women's Health Issues.

RESEARCH TRAINEES

Question. What is the status of the comprehensive report directed by this Committee describing strategies for achieving the goals recommended by the National Academy of Sciences in 1984 for pre- and post doctoral training in behavioral research?

Answer. The report on research training was forwarded to the Committee by the Assistant Secretary for Management and Budget on February 26, 1986.

Question. Why are you not asking for inflationary increases in stipend levels? How do you expect to maintain good researchers if we don't provide adequate allowances?

Answer. Historically, PHS has not provided stipend increases every year. Significant stipend increases were adopted in 1985. A stipend is intended only to defer part of the cost of the living expenses of a scientist in training; this is not intended to provide full support of the trainee. We believe that the level of stipend support currently provided is adequate to attract high quality researchers and retain them until they complete their research training.

Question. During last year's hearing, questions were raised about what information ADAMHA had on the success of its trainees in pursuing research careers, and the number of trainees who work in the field subsequent to the completion of training. A question was also raised about what steps are being taken to ensure that the agency is supporting high quality research trainees, in light of decreasing resources being available to support research training. The agency responded that a work group should be formed to examine these issues. What is the status of your efforts to address these issues?

Answer. ADAMHA has taken a number of steps to address the

questions raised during last year's budget hearing. The agency has been working with the National Academy of Sciences and NIH to improve the quality and accuracy of the data in the computer files which contain information on research trainees and fellows. This activity has recently been completed. We have begun to examine the data and develop some preliminary analyses. These analyses have revealed that, of Principal Investigators on FY 1984 ADAMHA research grants, approximately 28 percent had received prior research training support from ADAMHA. The number of ADAMHA grantees with prior ADAMHA research training is one indicator of those individuals who have continued to work in the ADM fields subsequent to completion of training.

In addition, in an attempt to gather more qualitative data on the success of our research training programs, both NIDA and NIMH are planning to conduct follow-up studies to examine the performance of institute-supported research trainees and fellows. These studies will be undertaken in late FY 1986-1987. In addition, we have been discussing with the Office of the Assistant Secretary for Planning and Evaluation, development of strategies for assessing research training outcomes and analysis.

The reorganization of the National Institute of Mental Health resulted in the decentralization of research training within the Institute. Research training is now supported in each of the NIMH component offices rather than from a central office. As each office has organized itself, it has looked at the research training program transferred to it to assess whether support is currently being provided in areas where the greatest need is projected, taking into account current available manpower in other related fields, projected numbers of awards, and the availability of new technologies in the field.

The initial review groups continue to rigorously review applications for research training awards, recommending only the highest quality applications for funding. Awarding components apply equally rigorous standards in deciding which applications to fund, particularly at a time of scarce resources.

ALCOHOLISM TREATMENT

Question. What has the study conducted in conjunction with HCFA found in regard to determining the placement of alcoholic patients in health care facilities appropriate to the severity of the patient's condition?

Answer. The specific purpose of the study is to determine (1) the feasibility of providing alcoholism treatment to Medicare and Medicaid clients in freestanding, nonhospital-based facilities, (2) Medicare and Medicaid costs and utilization of alcoholism treatment in such settings, and (3) the total Medicare and Medicaid health care costs and utilization before, during, and after treatment in such settings. The study is providing evidence of the feasibility of providing treatment to Medicare and Medicaid clients in free-standing settings. Thus far, 2,833 Medicare clients experienced 4,547 admissions in the over 100 facilities participating in the six-State demonstration. A total of 5,689 Medicaid clients experienced 8,526 admissions.

Preliminary data indicate that the various forms of treatment are approximately equally effective in reducing readmission frequency within one year following initiation of alcoholism treatment. Readmissions are significantly higher for clients who enter detoxification programs without followup treatment. Preliminary data also show sharp reductions in general health care costs after instituting treatment for alcoholism in the affected individual. The final project report is scheduled to be completed in December 1986.

CENTERS PROGRAM

Question. How are the Center programs affected by this smaller 1987 other research mechanisms allowance?

Answer. In 1986 we plan to fund all Centers at approximately 90% of the Council recommended levels. In 1987, in the event that our anticipated competing renewal applications are all approved with high priority scores, we could support these same Centers at approximately 68% of anticipated Council recommended levels.

Question. Are you funding them at their recommended level?

Answer. Within the funds earmarked for Centers grants in 1987, we would only be able to fund the Centers at 68% of their recommended level as compared to 90% of the recommended level in 1986 for the same number of Centers.

COOPERATIVE AGREEMENTS AND CENTERS

Question. What are we losing by the cutback in cooperative agreements and centers?

Answer. Among the cooperative agreements, we would not be funding four competing renewals. These agreements relate primarily to studies of the incidence and prevalence of mental illness, and to the processing of data gleaned from various depression studies. In the Centers program, we will make every attempt to maintain our current complement of centers if they all receive high priority scores; however, it is not likely that we will be able to support new awards.

SMALL GRANTS AND RESEARCH SCIENTISTS AWARDS

Question. RSDAs and small grants are methods employed, along with research training grants to encourage growth in the pool of researchers in the ADM field. In light of the reductions in new awards for RSDAs and small grants (40% and 50% respectively) are you not mortgaging the future of your research programs?

Answer. RSDAs and small grants were designed to support the research efforts of young and new investigators who might not otherwise have been able to successfully compete in our regular grant program. As a part of our efforts to make the most of the reduced level of funds in the FY 87 budget we have decided there is no choice but to cut the funds for these two programs. The RSDA program will be reduced by 11.4% and small grants will be

reduced by 51%. Given their future commitment base, new and competing RSD awards will thus go from 42 in FY 86 to 25 in FY 87. Small grants, being limited to one year, do not have future commitments and will be reduced from 74 in FY 86 to 36 in FY 87.

When grant funds are so limited, we feel it is important to keep in mind the primary goal of the Agency-- the support of research likely to provide new knowledge that will contribute to our ability to understand, prevent, diagnose, and treat mental illness, drug abuse, and alcoholism. The most direct way to accomplish this is the regular project grant. By committing the bulk of our resources to this mechanism all investigators must compete on a par, and we will be able to identify and support the very best research serving the mission of the Agency. RSDA and small grant funds support individual professional development, a legitimate goal, but one which in tight budget years must be sacrificed in favor of higher priority research projects.

OTHER RESEARCH MECHANISMS

Question. Last year Dr. Macdonald stated that the 24% of the agency's extramural research budget that was in "other research mechanisms" was low relative to their importance in the overall research priorities. For 1987 you are proposing to lower that percentage to 19%. What led to this decision to go counter to your priorities?

Answer. Even though the percentage of other research mechanisms is at 19% of the extramural research budget for 1987, we have not altered their priority. Funding priorities are first to regular, investigator-initiated research grants, second to our own excellent intramural research effort, and third to all other research mechanisms.

PREVENTION

Question. How is your agency working with local community groups to promote prevention efforts and assist in treatment?

Answer. The Office of the Administrator, ADAMHA, recently established the Office of Prevention to promote and coordinate the prevention research programs of the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and the National Institute of Mental Health as well as to promote and coordinate prevention research programs between the Institutes and other public and private entities. This administrative unit within the Office of the Administrator maintains contact with numerous community groups to facilitate knowledge transfer and dissemination of research findings.

At the Institute level, a number of national media campaigns have been initiated to address community level issues such as fetal alcohol syndrome, drunk and drugged driving, high school graduation/prom night abuse of alcohol, and cocaine use at the worksite. ADAMHA provides technical assistance and consultation to parent organizations (i.e, National Federation of Parents for

Drug Free Youth, PRIDE, and Youth to Youth) in order to facilitate prevention efforts within the community. Also, the National Institute on Drug Abuse utilizes a contract with PYRAMID to provide additional technical assistance to community groups. The PYRAMID project has assisted communities in virtually every state in the union.

All three Institutes maintain State and community liaison units for purposes of consultation, technical assistance, and dissemination of information and programs related to prevention, services, and treatment. Each Institute supports a public affairs unit which disseminates pamphlets, booklets, monographs, posters, and other publications relating to prevention and treatment. NIDA and NIAAA are co-sponsoring the First National Conference on Alcohol and Drug Abuse Prevention in August, 1986 as a national forum to highlight state-of-the-art information on prevention research, programs, strategies, evaluation and resources, as well as create new or extend existing networks.

Question. What are some of the practical applications of your research in regard to preventing and treating ADM disorders?

Answer. Prevention research enables us to identify high risk groups, high risk behaviors and high risk settings, and to assess and evaluate preventive interventions.

Since teenagers are a high risk group for ADM disorders, ADAMHA has targeted this group in media campaigns (i.e., "Just Say No" and "Project Graduation/Prom") as well as implemented the Secretary's Task Force on Youth Suicide. ADAMHA research findings have also suggested the importance of working with parents/families in prevention efforts. As a result, the "Fetal Alcohol Syndrome" initiative and ADAMHA collaboration with the Department of Justice (Office of Juvenile Justice and Delinquency Prevention) has been established. Educational programs alone are not sufficient to prevent adolescent experimentation with illicit substances. We now know that education, in combination with peer pressure resistance training, psychosocial skills building, and development of alternative behaviors have a better likelihood of diverting the progression into ADM disorders. We are supporting preventive intervention research projects that test these approaches. A fuller discussion of our prevention research findings and applications can be found in the FY 83 and FY 84 Prevention Activities Report to Congress.

Question. How can your agency and its research be more effective in the real world?

Answer. In an attempt to become more sensitive to the needs of the private sector, the Administrator has convened two roundtables. The "Prevention Roundtable" was used as a forum for prevention advocacy and service delivery leaders to discuss their needs. Recommendations were given to the Institutes and follow-up action on areas of concern have been and continue to be addressed. Members of the nursing profession were invited to present their needs at the "Nursing Roundtable." A tri-Institute liaison committee has been formed to respond to the recommendations that resulted from the Nursing Roundtable.

The ADAMHA Advisory Board recently held its initial meeting. Board members were appointed to represent all areas of the ADM research and service fields. The ADAMHA Advisory Board is another way to maintain an awareness of, and become more effective in, the real world.

In-house activities include a review of knowledge transfer policies and activities within the agency. ADAMHA has recently disseminated the proceedings of a major national conference entitled, "Knowledge Transfer Roundtable."

NIDA's Research Analysis and Utilization System (RAUS) is designed to classify the findings of all NIDA intramural and extramural research; evaluate the findings in selected areas of particular interest; disseminate findings to researchers and other interested persons; and provide a feedback mechanism to NIDA staff and planners. The Alcohol Research Utilization System (ARUS) is designed to facilitate the identification and prioritization of research findings and current knowledge which should be communicated to appropriate user communities in a timely manner.

ADAMHA has collaborated with Office of Juvenile Justice and Delinquency Prevention to convene two workshops regarding the state-of-the-art in services and the state-of-the-art in research related to the population of juvenile delinquents who also suffer from alcohol, drug abuse, and mental disorders. This review process will have significant ramifications for the future, e.g., follow-up technical assistance and funding of model approaches from these workshops. These proceedings will be distributed widely.

ADAMHA convened the first "Public/Private Sector Forum" in FY 86 to identify the needs of the private sector service delivery system. Recommendations from this activity are being addressed by various components within ADAMHA.

Question. How will the sequestering in 1986 and the reduced expenditures in 1987 affect your agency's efforts to meet the 1990 prevention objectives?

Answer. A 1987 reduction of expenditures could have some impact on attaining the 1990 Objectives for the Nation. In FY 85, ADAMHA completed its midcourse review which indicates that ADAMHA is making good progress towards the attainment of its 1990 objectives. ADAMHA has made a substantial temporal and financial investment in obtaining baseline data for monitoring progress toward achieving a number of priority objectives. These efforts warrant continuation because comprehensive national data are essential to measure accomplishment of the Objectives for the Nation. We anticipate the availability of sufficient budgetary allocations and resources to sustain surveillance mechanisms established in the first half of the decade. We need this capacity to monitor progress so that we will be able to determine the extent to which we met the 1990 prevention objectives.

MINORITIES

Question. What are your 1986 plans for expenditures in minority programs and what effect will the rescission and sequestration have on these programs?

Answer. ADAMHA had planned to expend approximately $34 million for all minority programs in fiscal year 1986 based on appropriated funds. This amount was comparable to our expenditures in fiscal year 1985. Due to the sequestration, minority relevant research and research training programs sustained a 4.3 percent cut across the board as did all other programs. As a result of the rescission, the Minority Fellowship Program will be reduced by $1.1 million and 99 trainees. This is due to the fact that approximately 60 percent of this program is supported with clinical training funds. In addition, $2.2 million in clinical training grants to minority and disadvantaged students will be affected by the rescission.

Question. What are your plans for 1987?

Answer. We plan to expend approximately $30 million for all minority programs in fiscal year 1987. This amount is comparable to our revised expenditures for fiscal year 1986.

Question. How much was awarded to Historically Black Colleges in 1985 and what are your goals for 86 and 87?

Answer. Historically Black Colleges were awarded approximately $2 million in fiscal year 1985. Our goal in fiscal year 1986 and 1987 is $2.1 million.

Question. What is the status of the report requested by this Committee last year from the Associate Director of NIMH for Special Populations?

Answer. The report from the Associate Director of NIMH for Special Populations was forwarded by the Assistant Secretary for Management and Budget to the Senate Appropriations Subcommittee on February 26, 1986.

Question. What has been the various impact of the various organizational changes in ADAMHA on programs targeted toward our Nation's minorities, including Hispanics?

Answer. There has been no dimunition in programs targeted toward our Nation's minorities, including Hispanics, resulting from the organizational changes in ADAMHA.

INTRAMURAL FACILITY REPAIR AND IMPROVEMENT

Question. You are requesting $400,000 for maintenance to ADAMHA's intramural facilities. Part of this amount will allow implementation of safety measures needed to accommodate molecular genetic research. Please explain briefly what measures are necessary to ensure the safety of the research staff and what dangers, if any, are posed to the staff if these improvements are not made.

Answer. Federal standards for recombinant work specify minimum standards that laboratories must meet in order to ensure the safety of both the research staff and the local community affected by the atmospheric emissions from the building. The annex to the Flow Building is well suited for the work. It is separated from the main building by a hallway through which traffic can be restricted. It allows the installation and maintenance of separate air-handling and electrical systems. Although these safety features are available, the structure itself will require considerable renovations. Insulation is needed for the walls, ceiling, duct work and pipes. In addition, sinks and a sewer line have to be installed; the roof needs to be repaired; and it must be rewired and have new electrical equipment (fixtures, panel boards, conductors). Finally, a new air-handling unit and condenser, humidifiers, reheat coils, air terminals, return registers, and control system are required to insure proper temperature control and the safety of those within the facility and in the community. Whenever scientists use recombinant substances, there is an assumption that they may be dangerous. Therefore, workers and environment should be protected. The planned renovations are in accordance with guidelines found in the CDC/NIH manual on biosafety in microbiological and biomedical laboratories, and the NIH guidelines for research involving recombinant DNA.

DIRECT OPERATIONS

Question. Your budget submission indicates that the direct operations portion of each institute is increasing for mandatory items, but then is offset by mandatory and program decreases. Please tell us what administrative overhead and program projects are being reduced.

Answer. In NIMH, the principal areas of focus for reductions are travel, the purchase of publications and subscriptions, and the purchase of services from consultants. NIMH is also effecting reductions in the number of meetings and conferences - particularly in relation to liaison and technical activities with State and local organizations.

In NIDA, the reduction associated with administrative overhead involves savings from various improvements in the efficiency of operations. A specific improvement will be in reducing computer service charges. These services are used for data processing associated with several epidemiological programs as well as various administrative systems. With the purchase of a minicomputer, which will be able to handle many of these programs, charges for computer services will be reduced. Because NIDA owns and operates the minicomputer with existing staff, these reductions will reflect actual savings in the cost of our operations.

In NIAAA, there is a mandatory decrease in costs for the service and supply fund and standard level users charges (SLUC); a reduction in administrative overhead for such items as postage and telephone service; and a reduction in contracts. The reduction in contract funding will be accomplished through a reduction in the number of contracts funded. Several of the contracts funded in 1986 will not require 1987 funding. Other projects, in support of prevention and research dissemination activities, will be eliminated.

Question. What effect will these reductions have on your research, prevention and training programs?

Answer. In NIMH, research activities have been held harmless although there will be reductions in support costs within the Intramural Research Program along with reductions in the size of some extramural research contracts. The effect on the Prevention program will also be minor, since most of the activity relates to the use of project grants. Research training will not be affected.

In NIDA, because these savings will be obtained through improvements in the efficiency of operations, they should have no effect on research, prevention and training programs.

In NIAAA, the reductions will primarily affect our ability to prepare and disseminate materials on research findings which are applicable to prevention and treatment programs.

COMMUNITY SUPPORT

Question. How many staff are currently assigned to CSP? What happens to them with these threats of rescissions?

Answer. A total of 11 employees is currently assigned to the Community Support Program. These individuals also have a major role with respect to the provision of technical assistance to States, and dealing with Block Grant issues. For this reason, they would continue to be needed even if there were a rescission of CSP funds.

Question. What are the continuation costs for these programs in 1987?

Answer: If the program is not rescinded and operates at the sequester level in 1986, the 1987 continuation cost would be $9,319,000. This total includes $3,960,000 for the adult program; $3,920,000 for the children's program; and $1,439,000 for research demonstrations.

Question. How many dollars have been invested since the CSP program started?

Answer. A total of $49.3 million has been invested since the program started in 1978. Of this amount, $41.8 million has gone to the basic CSP program; $5.5 million has been spent on the Child and Adolescent program; $1.7 million has been obligated for research projects; and $0.3 million has been used for technical assistance.

CASSP

Question. What States received grants for the children's initiative under CSP?

Answer. Ten CASSP grants were awarded in fiscal year 1984, to the States of Alabama, Alaska, Georgia, Hawaii, Kansas, Maine, Mississippi, New Jersey, Ohio, and Wisconsin. An

additional twelve grants were awarded in FY 1985, including Delaware, Idaho, Illinois, Indiana, Kentucky, Louisiana, Nebraska, New York, Oklahoma, Pennsylvania, Tennessee and Vermont. Therefore, a total of 22 States are in the second or third year of CASSP funding at this time.

Question. What kinds of things are being accomplished?

Answer. The new initiative for severely emotionally disturbed (SED) children and adolescents is being implemented by activities in three major program areas: State grants, technical assistance and resource development, and evaluation. With the $1.5 million earmarked by Congress in Fiscal Year 1984, NIMH funded ten State grants ($1.2 million) and initiated a technical assistance program which makes available to all States the latest knowledge concerning child mental health service and system development ($0.3 million). With a Fiscal Year 1985 appropriation of $3.9 million, CASSP funded an additional twelve State grants, such that its grant activities now impact the SED children and adolescents of nearly half the States.

In addition, a number of studies and knowledge-gathering activities are planned. They include preparation of a monograph on systems of care; conduct of a study of community-based service alternatives for SED children and adolescents; an effort to collect information on the financing of mental health services for SED children and adolescents; and a workshop and monograph on mental health program development for minority children and their families.

COALITIONS

Question. Please review the work that has been done to build coalitions within the community with regard to ADM disorders.

Answer. ADAMHA collaborates with a wide range of national, voluntary, and professional organizations in order to develop coalitions which will promote and market prevention campaigns and other communications outreach programs. The following represents some of the efforts that have been undertaken by the three ADAMHA institutes.

NIMH

- Planning/advisory groups have been formed in many states which include representatives from mental health, housing, vocational rehabilitation, Social Security, and welfare agencies and from family support and consumer self-help organizations. These groups engage in a participatory planning process that encourages assuming responsibility for both problems and solutions related to improving services for persons with long-term, disabling mental illness.

- In almost every State and locality, family support groups have been fostered. These groups are having

a direct impact on increasing the numbers of community programs and resources allocated to the population of the chronically mentally ill.

- In many localities coalitions of ex-mental patient groups are being established. These groups are promoting self and mutual help approaches for some clients as cost-effective alternatives to traditional mental health services.

NIDA

- The "Just Say No" Campaign, developed under the auspices of the Advertising Council, combined information from prevention research with knowledge gained in attitude surveys and focus group testing to develop an antidrug message for parents and early teens. The slogan, "Just Say No," has gained recognition and acceptance by Mrs. Reagan and prevention groups all over the country and even in other countries (i.e., Great Britain, Spain).

  Marketing of the campaign has encompassed over 500 groups, including the National Federation of Parents, the National Association of State Alcohol and Drug Abuse Directors, representatives of national coalitions of minority organizations, and others. This marketing activity has resulted in extensive use of the slogan and materials in local campaigns throughout the country. With NIDA's assistance, the National Broadcasting Company (NBC) will be carrying the "Just Say No" slogan in its media campaign this coming winter. They are promoting "Just Say No Clubs" for the elementary schools through written material sent to the schools, and broadcast on the air.

- NIDA is working with various organizations within the entertainment community about the specific issue of cocaine. Concerns about a potentially injectable drug, such as cocaine, and concerns about the spread of AIDS are readily joined. The focus of the activities proposed is two-fold: (1) by building on the existing coalitions NIDA has developed within the industry, NIDA proposes to educate them about the relationship between intravenous IV drug use and AIDS; (2) to encourage them to undertake activities that discourage substance use by employees of the community and reduce the threat to AIDS; and (3) to encourage activities that can exert an anti-drug influence on preteens, teens, and young adults, our primary audiences.

  After months of working with several organizations in the entertainment community, NIDA cosponsored a conference with the Alliance of Motion Picture and Television Producers, the Entertainment Industries Council and the National Council for Families and Television on cocaine abuse prevention in Los Angeles, California in November, 1985. The focus of the conference was on the addictive qualities of cocaine and Hollywood's ability to "take the glitter out of cocaine." It was the first such conference on cocaine in Hollywood and

represented an important step in having major entertainment organizations take a stand on cocaine.

NIAAA

- NIAAA has initiated a new major public education campaign to reach early adolescents before they are exposed to substantial peer and other pressures to drink. This campaign will be an integrated public education effort that includes community programming, local communication, and intervention strategies along with print and broadcast media efforts. In addition to these activities, NIAAA is also working with the National Association of Broadcasters and a number of other organizations on Operation Prom/Graduation, in order to reduce the number of alcohol and drug-related deaths involving teenagers during prom time.

- For the past few years, NIAAA has been involved with "National Drunk and Drugged Driving Awareness Week," a cooperative public/private and State/Federal prevention effort designed to raise community awareness of the dangers of driving while impaired by alcohol or drugs.

- NIAAA's campaign to address the fetal alcohol syndrome and other alcohol-related birth defects, has closely collaborated with the Public Health Service's "Healthy Mothers, Healthy Babies Coalition" to ensure that alcohol messages are included in the overall effort to increase the number of healthy babies born in the United States.

PREVENTION

Question. Please describe in detail the work being done in the area of prevention of ADM disorders.

Answer. The work being done in the prevention of ADM disorders falls within three broad categories: research, research/clinical training; knowledge transfer/dissemination; and consultation/technical assistance. Prevention is an integral part of the extramural and intramural research components of the Institute's comprising ADAMHA.

In FY 84, prevention activities at ADAMHA comprised approximately 10.4 percent of its total research budget, and research grants were coded to prevention.

A detailed description of the depth and breadth of this agency's commitment to prevention activities can be found in the FY 83 and FY 84 Reports to Congress on the prevention activities of ADAMHA. The FY 85 Report is currently undergoing internal review before final submission to Congress.

DISTRIBUTION OF GRANTS BETWEEN INSTITUTES

Question. Please explain why that in 1987 there seems to be a disproportionate number of new grants in mental health research as compared to alcohol and drug abuse research when compared to the distribution in 1980?

Answer. Much of this apparent imbalance is the reduction of 35 new grants that NIMH had to make to provide for an unexpected additional 35 continuation grants in 1986.

Question. Please explain in detail the reasons for the increase in average costs.

Answer. A number of factors appear to be contributing to increasing average costs of grants. We have a work group looking into these factors and considering what actions might be appropriate in response to these increases. One of the factors we have noted to date is the higher cost of doing research in high priority areas of national need (e.g., prevention and epidemiology) and in areas of rapidly expanding technology and scientific opportunity (e.g, the neurosciences). ADAMHA has been increasing its level of effort in these areas in recent years, and this is part of the explanation for the increase in average costs. The work group is still in the process of analyzing the information which they have collected. We anticipate that a report will be available around late April, 1986.

OTHER RESEARCH MECHANISMS

Question. The 1987 budget maintains research project grants at relatively stable levels, while substantially reducing other types of extramural research mechanisms. Does this reflect a conscious desire to favor investigator-initiated research, or were there other considerations involved?

Answer. Our first priority in allocating funds to support our research efforts is with investigator-initiated, regular research awards. These grantees, over the years, tend to provide the majority of research breakthroughs and other major accomplishments. Our second priority is to support our own outstanding intramural research effort at a level that provides at least current services. Remaining funds are utilized in supporting all other research mechanisms, some of which are investigator-initiated, with concentration on supporting continuations.

SECTION 515 REDUCTIONS

Question. What impact will the Section 515 reductions have on your research program?

Answer. A total of $650,000 will be reduced from the NIMH research contracts program. The major areas affected will be the processing and collecting of data from depression studies, evaluation studies and studies on the organization and delivery of mental health services.

The Section 515 reduction of $264,000 in NIDA will result in the elimination of three planned consultant services contracts intended to improve our drug abuse data collection activities. These include a heroin prevalence study intended to develop better methods for collecting data on the number of heroin users in the

country; a medical examiner field study, intended to develop a pilot study of a research oriented, prospective reporting system in a selected sample of medical examiner offices to collect more and better information on drug related deaths; and a feasibility study for a National Survey of Drug Abuse Treatment Programs; intended to study the feasibility of conducting a national survey of treatment facilities in order to obtain information on the numbers, characteristics, and problems of people seeking drug abuse treatment.

In NIAAA, the Section 515 reduction of $178,000 will be absorbed by eliminating 4 contract projects to support a collaborative effort with NIDA and the States to collect alcohol and drug data; a national survey of treatment programs; planning NIAAA/NIDA research workshops; and a joint research initiative with the National Cancer Institute.

SUPPORT FOR CSP

Question. With the cessation of Federal funding for Community Support Programs (CSP) as your budget proposes, what are the prospects for the future support for such programs from other sources?

Answer. It is expected that the States would continue to support CSP activities with State and other mental health funds. These activities would include a continued focus on increasing and improving psychosocial rehabilitation services for the population; an ongoing promotion of family support and consumer self-help groups; and special efforts to address the needs of subgroups of the population such as the homeless, the elderly, and young adults with severe, disabling mental illness.

As assessment of future prospects can be based on current evidence that the States have already made substantial progress in this regard. Funding for approximately 45 programs, initiated originally with CSP seed funds, has been continued by the States. For example, Alabama picked up funding for a case management program in Birmingham once the CSP funds ended. In addition, many States have continued funding CSP staff positions formerly supported by Federal funds. Therefore, the prospects are good that some of the States will continue to provide support for some of the efforts stimulated by the Federal CSP program.

Question. What evidence do you have that States will be willing or able to provide funding for CSP from their ADM block grant allotments?

Answer. Almost every State has designated as its priority target population for services the long-term mentally ill and are already using a significant portion of ADM Block Grant funds to support direct services to that population through Community Mental Health Centers. It is anticipated that States will continue to apply the knowledge and principles learned through past participation in the CSP program to the critical planning needed to address the problems of the long-term mentally ill. Approximately half of the States have undertaken a reorientation in approach to psychosocial rehabilitation, and

the same proportion of States has passed legislation or appropriated new funds on behalf of programs for this population. Therefore, there is strong evidence to suggest that most States will use available resources, including ADM Block Grant funds, to continue the basic direction of the CSP philosophy.

Question. What would be the impact of using ADM block grant funds to support CSP type activities on other activities funded through the block grants, such as the community mental health centers?

Answer. At present most CMHCs are using a portion of ADM block grant funds to provide outreach, psychosocial rehabilitation, and case management services as part of local community support initiatives for persons with long-term, disabling mental illness.

The impact of using block grant funds for additional CSP activities is that CMHCs would have fewer resources available for consultation, education, employee assistance, and other clinical activities.

Question. Have any CSP activities focused on the problems of the homeless mentally ill and how to help them? Please give examples.

Answer. A number of CSP activities have focused on understanding the demographics and needs of the homeless and how to assist them. The following are some examples:

- In 1983 seven grants were awarded to States and research organizations to conduct studies to determine the size, characteristics, and service needs of the population. Periodic meetings of the researchers have provided the opportunity to assist each other and exchange results. The findings of these studies are being disseminated to all States.

- In 1985, six States received funding to demonstrate innovative approaches to involving the homeless mentally ill in services. For example, Kentucky is studying a coalition-building approach through engaging approximately 20 agencies in collaborating on planning, case management, securing financial support, and outreach on behalf of the mentally ill homeless in the metropolitan Louisville area. Washington is establishing a client-operated hygiene center in Seattle that will provide an inconspicuous entry point into the mental health system for reluctant, fearful homeless persons.

- In 1986, approximately 8 three-year mental health services demonstration projects will be funded to implement and evaluate community programs to assist homeless mentally ill persons obtain needed life support and mental health services. The results will be disseminated nationally.

- Workshops on helping the homeless mentally ill have been conducted at a number of national, regional and State CSP conferences during the past five years.

AVERAGE COST OF RESEARCH GRANTS

Question. At what cost do you expect to fund your FY 1987 research grants compared to FY 1984, 1985 and 1986?

Answer. The average funded grant of new and competing grants in 1987 will be $132,321. The average funded costs in 1984, 1985 and 1986 are $114,113, $128,744 and $130,057, respectively.

Question Submitted by Senator Arlen Specter

CLINICAL TRAINING

Question. In the proposed budget request, which cuts off all funding for mental health clinical training programs, you state that long-term Federal support for clinical training has resulted in a national training capacity which will continue to function productively without further Federal subsidies. If this is the rationale, does this mean that private funding alone will totally finance this form of training, and could you elaborate on how these programs will be maintained, in light of proposed budget cuts?

Answer. Mental health clinical training programs are part of graduate education in public and private universities and schools of medicine, nursing, and social work throughout the Nation. For the most part they are maintained with university funds derived from tuition, taxes, gifts, endowments, etc. In past years NIMH grant funds contributed substantially to the growth of these departments and provided stipends for a large number of students. In the recent past, however, NIMH support has decreased while department budgets have risen sharply. In FY 1985 the average NIMH grant for mental health professional clinical training was approximately $41,000 and funded two or three stipends. This is only a small fraction of the department's training budgets and there probably would not be a major impact if these Federal funds were discontinued. The impact would be greater on programs in psychology, nursing and social work than those in psychiatry because psychiatric residents--as fully licensed physicians--can generate income from fees-for-service to cover some of the costs of their training. This is not true for the nonmedical disciplines.

Further evidence for the limited impact of discontinuance of Federal clinical training funds is the fact that enrollment in graduate mental health training programs has not declined for psychology, psychiatry, or nursing in the years since NIMH support was reduced. Enrollment has dropped for graduate social work education, but this may be primarily due to a tight employment market and the lack of jobs, not to the decrease in NIMH support.

Questions Submitted by Senator Pete V. Domenici

RESOURCES FOR BREAKTHROUGHS

Question. In light of the recent extraordinary breakthroughs in the neurosciences and behavioral sciences, I am very concerned that your agency has the necessary resources to make timely use of these advances. I am concerned that new avenues of research are pursued as early as possible to enhance our understanding of the manifold causes of schizophrenia and other serious mental illness. I know many families would be most happy to see even the slightest hope in new treatment modalities resulting from our expanding knowledge base. Please give me a thorough explanation of your efforts to make the best use of new breakthroughs to explore new research potential and to treat the mentally ill.

Answer. Given the resources available, we are trying as best we can to move the field of mental health research forward by taking advantage of recent breakthroughs and new technologies in molecular biology and genetics, peptide neurotransmitters, brain imaging techniques, immunology, and neuroplasticity. Specific efforts have been made in our Intramural Research Program to capitalize on these new research opportunities by redirecting resources and restructuring programs to create new laboratory units. For example, the new Laboratory of Molecular Biology brings together expertise in recombinant DNA technology, monoclonal antibody technology brain receptor-ligand interactions, and the regulation of nerve cell events by second messenger systems. These cutting edge disciplines have been converging and the synergy and economics of scale afforded by combining them in a single laboratory promises to yield a rich output. Collaborative efforts with NIH Institutes has also resulted in optimal allocation of resouces to make the best use of recent advances in high technology areas for clinical brain imaging. By applying the technique of Positron Emission Tomography (PET scans), important new results have been obtained in studies of patients suffering from chronic schizophrenia. A significant decrease in metabolic activity was found in a specific area of the brain coincident with a complex task involving abstract reasoning. This represents the first time that a localized deficit has been demonstrated in this illness. It is hoped that this avenue of research will enhance our understanding of schizophrenia and lead to improved treatment modalities.

The efforts of the NIMH Extramural Program staff are directed at stimulating and encouraging investigators in the field who have the necessary expertise and resources to explore the research potential of new methodological breakthroughs in molecular biology and brain imaging techniques so that these can be quickly applied to brain science and mental health research. To inform clinical investigators in psychiatry of the extraordinary breakthroughs in the neurosciences, NIMH has disseminated a publication, "The Neurosciences of Mental Health." This monograph highlights research areas where new breakthroughs are possible and where additional research is needed. In addition, a new branch, Health and Behavior, was formed within the Division of Basic Sciences as a result of the recent reorganization of NIMH extramural programs. This will further our efforts to translate exciting new leads in basic brain

and behavior research into projects that emphasize psychoimmunology, stress and behavior, and behavioral medicine. These areas will integrate new concepts and advances in neurobiology into mental health research and treatment of the mentally ill. The efforts on the part of our Extramural Program staff are showing tangible results in terms of many high quality new research grant applications.

MENTAL HEALTH RESEARCHERS

Question. For the longer term, there has been much discussion about the incentives needed to attract the most capable researchers into the mental health fields. While I frequently hear the opinion that we are losing talented researchers to other fields, I do not have any solid evidence. Please inform this committee about the degree of seriousness of this problem for the future of mental health research.

Answer. Research in the mental health field has grown in importance and promise over the past decade, yet the pool of skilled researchers continues to lag behind other branches of medicine. The 1985 report on biomedical and behavioral research personnel needs from the National Academy of Sciences provides a compelling analysis which indicates the seriousness of the problem. The data show a dramatic comparison between research faculty in psychiatric departments and other fields of medicine. For example, 34.1% of all faculty with M.D.'s in other medical departments have at least one year of postdoctoral research training, while only 12.4% of psychiatric faculty have had that research training. Two-thirds of the general medical faculty members participate in some research, but only about half of psychiatric faculty do. Furthermore, 13.4% of all M.D. faculty are Principal Investigators on a research grant approved by NIH/ADAMHA, compared with only 4.9% in psychiatry. Such comparative figures demonstrate that a serious shortage of skilled researchers in the mental health field is likely to occur in the future when the momentum for research should be increasing. To respond to this need, the Institute has made more deliberate efforts to promote research careers in mental health. In addition to fellowship programs in conjunction with our Clinical Research Center grants, new grant programs such as the Physician Scientist Award, the Clinical Investigator Award, and the New Investigator Research Award, were recently established.

EMPHASIS ON PRIORITIES

Question. The Acting Administrator of ADAMHA has formally informed this committee of a "policy decision to devote an increasing annual share of its research budget to this area - even if the total research dollars do not increase." Please give this committee some concrete evidence of your efforts to improve the priorities and proportion of funding that is planned for serious mental illness in the immediate future. I would like to see this evidence against a background of your current and past priorities for mental health research (1984 - 1988).

Answer. The table below indicates that the NIMH budget request reflects the priority research areas selected by the

Institute. The data show that NIMH is increasingly allocating its research funding, even after sequestering, to basic research on the brain and behavior and to serious mental illness - defined as schizophrenia, depression, disorders of children and adolescents, and mental disorders of aging. Although not visible in the table, funding for depression research is being decreased to strike a more equitable balance between depression and the other serious disorders.

	1984	1985	1986	1987
Brain/Behavior	32.9%	33.4%	34.6%	35.3%
Serious Illness	42.6	42.5	42.7	43.0
Other areas	24.5	24.1	22.7	21.7

NIMH expects to maintain the same priority areas for the immediate future.

RESCISSION

Question. My colleagues are well aware of my deep interest and support for increased research and services relating to mental illness. Many of us worked diligently last year to increase federal support for these activities. The ADAMHA programs, including the mental health programs, all took a reduction as mandated by Gramm-Rudman-Hollings, and I have no problem with that. However, I fail to see why the Administration should then propose additional rescissions of FY 1986 budget authority totaling $20.1 million for the community support and clinical training programs, and $9.6 million for a new protection and advocacy program.

What is the Administration's rationale for the proposed rescissions?

Answer. The Community Support Program initially was intended to be a demonstration of limited duration and to cover only a few States. The program has gone beyond the original scope and funded adult-focused programs in all 50 States and the District. The child-focused program will have provided two years of demonstration experience by the end of FY 1986.

When the NIMH clinical training program was established in 1950 there were only 5,000 psychiatrists in the country. The profession of clinical psychology was in its infancy and there was no graduate level specialty in psychiatric nursing. Social work had not developed a focus on mental health. NIMH support was instrumental in building academic mental health training departments, improving the quality of training, and greatly increasing the numbers of mental health professionals. The clinical training program has shaped and built the national training capacity to the point that the training community will continue to function productively without Federal support.

Although the Administration acknowledges the value of efforts at providing protection and advocacy services, it considers these new programs unsupportable in view of the overall budget reductions required to reduce the Federal deficit. An increasing

number of States have initiated protection and advocacy initiatives; all States have responsibility for assuring that mental health services are provided and, then, for monitoring those services.

Question. How do such proposals affect our efforts to improve the treatment of the mentally ill?

Answer. For the reasons stated above we believe the States now have the necessary capacity to continue their own activities directed at improving the treatment of the mentally ill.

Question. How do such proposals affect our efforts to improve the public understanding of the "illness" nature of mental disorders?

Answer. States and citizens' organizations, such as the National Mental Health Association and the National Alliance for the Mentally Ill, now are leading national efforts to improve public understanding of mental illness.

SCHIZOPHRENIA

Question. ADAMHA's Acting Administrator, Mr. Trachtenberg, recently submitted a "Report on Schizophrenia Research" requested by this Subcommittee in the FY 1986 appropriations report. In that report, NIMH indicates that approximately $21.1 million will be the FY 1986 investment in NIMH schizophrenia research.

Is this level of support the post-sequester level of funding? In other words, does the $21.1 million figure reflect the reductions implemented on March 1st under the Gramm-Rudman-Hollings Act?

Answer. The $21.1 million figure is the post-sequester figure. It takes into account the changes resulting from the Gramm-Rudman-Hollings Act, reducing combined expenditures for intramural and extramural research on schizophrenia from the originally appropriated level of $21.6 million. This reflects a net $2.68 million increase in the Institute's support for research on schizophrenia over 1985 levels.

Question. What level of support do you assume for schizophrenia research under the President's FY 1987 budget request?

Answer. The President's budget request would provide $21.1 million in support for schizophrenia research. This figure represents a 6.6% increase for intramural research and a 2.7% reduction for extramural research, with essentially no overall change from the sequestered level of the 1986 allocation.

Question. ADAMHA's "Report on Schizophrenia Research" indicates that NIMH does not establish a certain percentage of its research budget for any particular disorder, but rather independent review is given to the scientific merit of research

proposals. Can you assess the general quality of the research proposals submitted on schizophrenia?

Answer. The general quality of the research proposals submitted in schizophrenia remains exceptionally high. The peer review system functions to ensure the standards of research in all clinical disorders. The recent reorganization of the National Institute of Mental Health maintained the stability of the peer review system, which judges the quality of all research on mental disorders. For example, schizophrenia, affective disorders, child and adolescent mental disorders are reviewed by the same initial Review Groups applying the same sets of standards.

The recently completed reorganization of NIMH established a Schizophrenia Research Branch in the newly created Division of Clinical Research. One of the goals of this restructuring was to bring together in one administrative entity professional staff with many years of experience in the conduct and administration of research with a direct impact on schizophrenia. Through this Branch, we will now be able to more carefully monitor the NIMH portfolio and consult with investigators in schizophrenia to further ensure a high quality program in this area.

Question. How would you characterize the interest of the research community in this disorder?

Answer. Because schizophrenia is a complex disorder and difficult to study it has not always attracted the kind of sustained attention from researchers that is necessary for significant progress to be made.

Question. Do you expect that the interest in schizophrenia research will match NIMH's plans to increase the proportional level of funding in this area over the next several years?

Answer. There is a strong cadre of investigators who have a longstanding and deep commitment to research in schizophrenia. However, the Institute recognizes that there needs to be an increase in the number of high-quality scientists conducting schizophrenia research to match the plans for an increase in funding over the next several years. A recent meeting on incentives and disincentives to research careers addressed this question and NIMH staff have formulated a plan to attract and retain promising scientists for schizophrenia research.

Questions Submitted by Senator Alfonse D'Amato

COCAINE REPORT

Question. I have submitted legislation (S.772, The Cocaine and Health Reporting Act) to require a report to the nation on the health effects of cocaine. A copy of this bill, and my statement for the record introducing it, are provided.

Please provide this committee with an estimate of the cost to the National Institute on Drug Abuse of providing such a report?

Answer. The National Institute on Drug Abuse is currently preparing material for a Congressionally mandated report on drug abuse and drug abuse research. This report, to be submitted by the Secretary of Health and Human Services every three years, will be forwarded to the Congress on January 1, 1987. Since it will include the latest information available on the use and adverse health consequences of cocaine we believe it fulfills the need for a separate report on cocaine, avoids duplication of effort and the additional expenditure of scarce resources.

The Triennial Report currently under development is expected to cost approximately $60,000.

COCAINE RESEARCH

Question. In the January, 1984 Triennial Report to Congress, the Secretary of Health and Human Services states that there is a need for greater attention to many of the scientific and therapeutic issues surrounding cocaine abuse. Some of the issues this report mentions are highlighted in my Congressional Record statement introducing S. 772.

Please provide this Committee with a brief statement regarding NIDA'S ability to answer these outstanding questions with its present budget.

FROM THE CONGRESSIONAL RECORD MARCH 28, 1985

cf. "evidence of cocaine's addictive capability is only preliminary"

"what is not well appreciated is the quite different spectrum of effects and consequences at higher and more frequent doses"

"although organ damage has not been noted in humans, it has been noted in laboratory animals"

"other questions concern cocaine's ability to induce psychosis and the effects of cocaine when used with other drugs or with the additives to cocaine sold in the illicit market"

Answer. Since 1984 when the Triennial Report was delivered to Congress, the addictive capability of cocaine has been established with some certainty. Animal studies have shown that cocaine may be the most powerfully addicting drug known to man. From the human studies that have been completed, few would argue that cocaine is not addictive -- tolerance is developed, repeated self-administration of the drug is observed, and withdrawal symptoms (e.g., dysphoria) are noted when the drug is discontinued. Current studies of treatment for cocaine dependence are examining the use of such pharmacological agents as tricyclic antidepressants to relieve withdrawal while psychotherapies aim to change behavior and cognitive orientation.

Additional preclinical studies will be undertaken to characterize organ damage in humans similar to that found in laboratory animals. These studies will examine the pulmonary

effects of cocaine smoking and the toxic effects of cocaine on the central nervous system using advanced computer aided imaging techniques.

The physiological consequences which come with chronic, frequent self-administration are well documented in the available research; central nervous system stimulation, cardiovascular effects, and, in overdose, convulsions, cardiac abnormalities (e.g., arrythmia) and death. Current NIDA-sponsored research is examining dose-related behavioral effects, as well as patterns of psychopathology in cocaine users. More complete information on specific dose/frequency relationships should be available by FY 1987.

Cases of cocaine psychosis have been noted in the literature. As with other stimulants, transient psychotic episodes have resulted from prolonged, repeated use. A study of psychopathology among cocaine users is currently being carried out by Dr. Bruce Rounsaville under a NIDA grant, and some preliminary findings should be available by FY 1987. As for drug interactions, studies in two grants will focus on the physiological and behavioral effects of known doses of cocaine alone and in the presence of other drugs. Some preliminary findings will be available by FY 1988. Regarding effects of additives/adulterants in street cocaine, it should be noted that information on some of the most common adulterants (e.g., methamphetamine, benzene) are already in the literature.

The FY 1987 budget provides sufficient funds to make progress on all of these areas. While the total number of new and competing grants will decline from 131 in FY 1986 to 117 in FY 1987, we will be able to redirect funds from other important, but less crucial areas to support all high priority research on cocaine.

SUPPORT OF AGING CENTERS

Question. A letter from NIMH to Senator D'Amato states "Mental disorders of later life represent a significant priority area for NIMH". In FY 1984, three clinical research centers were funded to focus on the psychopathology of the elderly. In FY 1985, two additional centers were funded. It has come to my attention that one of these centers was not competitive enough to warrant renewal. Do you intend to fund another center in order to maintain five total centers, in accordance with the wishes of the Committee as was expressed in the FY 1986 Appropriations bill?

Answer. We would like to have maintained five centers on aging; however, for financial reasons, we will not be able to do so.

Of the four remaining aging centers to be funded, all have come back in 1986 with recommended support levels considerably in excess of the originally estimated amounts. As a result, even to fund one less center will require cutbacks, in all centers, below recommended levels. To support a fifth aging center could push the average cutback beyond 10 percent, and thus risk an unacceptable degree of program curtailment.

Although we will not be able to support five aging centers, it should be noted that the dollar investment in the remaining four will be approximately $200 thousand higher than the amount spent in 1985. Thus, although spread over fewer centers, the level of program effort will be maintained.

Questions Submitted by Senator William Proxmire

SEVERITY INDEX

Question. Mr. Trachtenberg, as you know the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA) submitted a report in February on alcoholism treatment research accomplishments and plans with particular emphasis on patient placement. Of course if we could treat more alcoholics on an outpatient basis rather than in hospitals we could save a substantial amount of money.

The report mentioned that research is underway on procedures to measure the severity of alcohol dependence. Do you think that an agreed upon and commonly used severity index for alcoholism and drug abuse can realistically be developed and utilized.

Answer. There are recent advances in biomedical screening instruments to test for alcohol and drug abuse. These, coupled with psychological testing and questionnaire data, can be combined to formulate more accurate appraisals of the severity of alcohol dependence. It is quite likely that a relatively inexpensive, highly accurate battery of tests can be assembled for use on a general scale. We estimate that within five years such instrumentation can be readily marketed in an inexpensive form. Work currently underway in the NIAAA Intramural Laboratories, for example, has found important links between serotonin levels in the brain and alcoholism and impulsive, aggressive behavior. Other research, currently underway, has linked certain imbalances in neurotransmitter precursors (e.g., tryptophan) and alcoholism, depression, suicide and aggressive behavior. It is important to note that this has important therapeutic implications since tryptophan therapy may help alcohol and drug dependent persons in lessening depression, suicide attempts, and violent behavior.

REPORT ON ALCOHOLISM TREATMENT

Question. The report also referred to a task force, with senior representatives from each of the three Institutes, charged with developing an agency-wide reimbursement and coverage policy agenda.

Can you tell the Committee what progress this task force has made to date?

Answer. The task force has met regularly over the last six months and has made significant progress in developing the information necessary to address industry concerns raised regarding that portion of HCFA's September, 1985 rule affecting MDC-20/DRGs (Major Diagnostic Category Number Twenty/Diagnosis Related Groups). Specifically, the task force chairman has met with representatives of the provider industry, synthesized their concerns, and implemented a reabstracting study to support analysis of DRGs contained in MDC-20. Additionally, the task force is developing proposals for an ongoing series of coverage policy and financing initiatives at the ADAMHA level.

Question. Does the task force plan to make recommendations regarding Medicare coverage as well as coverage by private insurers?

Answer. The task force has not been limited in its charge. They are currently developing an agenda to address facets of coverage and reimbursement policy that include Medicare, Medicaid, private and public insurance. I do expect, however, that Medicare coverage issues will be among those considered by the task force over the long run.

SCHIZOPHRENIA

Question. Dr. Frazier, I was encouraged by ADAMHA's report to the Committee on schizophrenia research but somewhat disappointed by the report's pessimistic outlook regarding the prospects for substantial progress in the near future. This is a disease that costs the American people $20 billion a year so any significant breakthrough would not only help to mend a great many shattered lives but would also save a great deal of money. Your report to the Committee indicates that "for the foreseeable future, the Institute has made a policy decision to devote an increasing share of your research budget to schizophrenia". I'll grant you that the share of your research budget devoted to schizophrenia research goes up somewhat in 1987 -- by about 1.3 percent. But do you really think that an increase for schizophrenia research from 9.5 percent of your budget this year to 10.8 percent of your budget in fiscal year 1987 represents a solid commitment to increased emphasis on schizophrenia research?

Answer. Senator, the figures you cite are correct. In the context of Gramm-Rudman reductions, the 1.3% increase over the 1985 level to which you refer is a substantial commitment to increased emphasis on schizophrenia research. Examined differently, the President's 1987 budget request would provide 14.46% more funds for schizophrenia research than were available in FY 1985.

Question. Your report to the Committee on schizophrenia research alludes to the need to attract the best scientific talent to this field. It goes on the say that you are now determining "the most effective and practical incentives for encouraging schizophrenia research careers."

Have you reached any preliminary conclusions and when will you make your final recommendations?

Answer. Dr. Shervert Frazier, Director of the National Institute of Mental Health convened a consultant's meeting on Incentives and Disincentives for Schizophrenia Research Careers in July, 1985. The theme of the meeting was the concern about difficulties in attracting and retaining the most promising scientists for schizophrenia research. The apparent causes of the shortage of well-trained research personnel or disincentives for research careers are multiple and complex. To some extent they reflect generic disincentives for clinical research careers in mental illness areas. In addition, the nature of the illness, the methodologies and approaches for its study, and the settings where

schizophrenia research is performed all potentially limit the attractiveness, satisfaction, and and career enhancement possibilities--all important for personal and professional motivation for young scientists. As the consultants pointed out, there are many reasons for scientists to leave schizophrenia research, too few to attract them into it. What was also clear from the meeting was that research careers develop in settings where research is ongoing. It is not only a salary stipend for young researchers that is important; an ongoing research environment and the possibility of research support are critical ingredients. Based on the advice of the consultants, recommendations in the areas listed below were prepared and presented to the March Meeting of the National Mental Health Advisory Council. The recommendations will be implemented as budgetary constraints permit

RECOMMENDATIONS FOR SCHIZOPHRENIA RESEARCH CAREER INCENTIVES*

I. Clinical Research Centers
II. Biologic Subtyping Program
III. Priority Funding of Schizophrenia Research
IV. Research Training Stipends
V. Scientific Stimulation

* A full report of the recommendations is available.

Question. The report on schizophrenia research indicates that you are considering the relocation of your intramural schizophrenia research program from St. Elizabeths Hospital to the main NIH campus where you have a much more sophisticated assortment of research tools.

Why wouldn't this clearly be a wise move? Why is further consideration needed?

Answer. We agree that relocation to the NIH campus is clearly a wise move for our schizophrenia research program. However, because such a move would require the construction of new or expanded facilities, it has been necessary to explore options for achieving this move within limited financial resources. At present, adequate space does not exist on the NIH campus for the program.

Question. When will a decision on relocating the intramural schizophrenia program be made?

Answer. A decision to relocate the intramural schizophrenia program will be made when adequate space becomes available at NIH, and access to a sufficient number of patients can be assured.

Questions Submitted by Senator Daniel K. Inouye

MINORITY FELLOWSHIP PROGRAM

Question. Last year both the House and Senate Committee reports expressed concern over an effort by NIMH to change its criteria for allocating awards under the Minority Fellowship Program in FY 85. The Committee indicated its interest in seeing

NIMH continue to apply the kinds of objective criteria used in the past, such as priority scores, program success, etc., in FY 86. Would Dr. Frazier comment on the criteria used in FY 86 and tell the Committee whether there are any changes in the process proposed for FY 87.

Answer. Priority scores and the history of program success will be the primary criteria used to determine funding of the Minority Fellowship Programs in FY 86. As a part of the overall reorganization of the Institute, all minority focused research training has been consolidated with the Minority Research Resources Branch in the Division of Biometry and Applied Sciences. An Institute Task Force is reviewing all of our efforts to improve and increase the training of minority persons for research careers in mental health. The Task Force will develop options that will be presented to the National Mental Health Advisory Council for their consideration in September, 1986. Council's recommendations concerning the allocation of awards and specific criteria will be the basis for FY 87 allocations.

RESEARCH TRAINING

Question. The Administration budget proposal would cut NIMH research training funds from $18 million to only $15.8 million. These funds would allow NIMH to support only 751 trainees, down from a high six years ago of 1,350. This consistent decrease in numbers of research trainees funded by NIMH makes it increasingly difficult to ensure an adequate supply of well-trained scientists in the area of mental health research. The National Academy of Sciences' 1985 report, "Personnel Needs and Training for Biomedical and Behavioral Research," projected a severe shortage of researchers trained in behavioral sciences at the doctoral level during the next decade and recommended that NIMH increase support of predoctoral and postdoctoral research trainees. The NAS report contained specific recommendations on restoring the number of NIMH predoctoral research training awards to the 1981 level of 650 and the number of NIMH postdoctoral research training awards to 540 by 1987. I would like Dr. Frazier to give his views on how NIMH is planning to provide research training for an adequate number of behavioral scientists, given both the proposed 12.7 percent cut in NIMH research training funds in the FY 1987 budget and the NAS projections of a severe shortage of researchers trained in the behavioral sciences over the next decade.

Answer. The Committee on National Needs for Biomedical and Behavioral Research Personnel detailed its assessment of the supply, academic production, and employment trends of research and academic personnel in the broad areas of biomedical sciences, behavioral sciences, clinical sciences, health services research, and nursing research, and made recommendations for the number of students who should receive PHS support in each of these areas. It is important to note that no recommendations are made separately to NIH, ADAMHA (or NIMH), or HRSA, the PHS agencies that make National Research Service Act awards.

Considering the overall picture of budget constraints, NIMH will concentrate its training efforts on the most important and promising research areas in the behavioral sciences and on

training people to use new technologies. The need for innovative approaches in mental health research underscores the future need for researchers skilled in new methodologies.

CHILDREN AND YOUTH

Question. In light of the growing concern over the plight of children and youth in this country, the Committee is most interested in learning of NIMH priority areas for this population. In particular, we would appreciate hearing about the current operation of the Child and Adolescent Service System Program, the Alcohol, Drug Abuse and Mental Health block grant, the developmental laboratory, and other ongoing and planned prevention, service and research programs specifically targeted at children and youth. Would you also comment on NIMH activities concerning child abuse and youth suicide and collaborations with other agencies in these areas.

Answer. Children and youth constitute one of the priority areas for NIMH. This is reflected in many ways including the following:

- The Child and Adolescent Service System Program awarded 12 new grants to States in FY 1985 to improve service delivery for severely emotionally disturbed youngsters; this brings the total States with such awards to 22. FY 85 funds were also used to provide technical assistance to funded States. Future plans call for several regional training and knowledge dissemination conferences for both funded and unfunded States and for other dissemination activities and knowledge-gathering efforts.

- The NIMH serves as the lead institute for children and youth within the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). Preliminary indications are that the States have moved forward with planning for initiatives directed to severely disturbed children and adolescents under ADM block grant legislation. Detailed information is expected to be derived from State annual reports which will be used for a statutory set-aside report to Congress, due October 1, 1986. Also, youngsters constitute the highest priority group for preventive services in the area of alcohol and drug abuse under the block grant.

- The Laboratory of Developmental Psychology in the NIMH intramural research program is focusing on 3 major areas: 1) the development of children brought up by depressed parents (interest in both genetic and environmental factors); 2) the experience of young children with problem behaviors as they advance in age to the school years (this is producing predictive data); 3) the problems of early adolescence--focus on the interplay of pubertal changes in relation to current and subsequent social, emotional, and cognitive characteristics.

- A significant proportion of the Institute's activity in prevention is being directed to children and youth. There is continuing interest in identifying risk factors for mental

illness and in carrying out research on preventive interventions.

- Service-related research includes interest in the roles of primary health care settings for child mental health and in the financing of mental health care for children and adolescents. These are expected to be continuing areas of NIMH attention.

- The Institute has a continuing interest in research on child development as it relates to mental health issues; this includes foci on intellectual, emotional, and social processes and problems that can occur in relation to them. There is also interest in family processess and in problems that can arise from pressures on families.

- Research on the clinical disorders of children and adolescents is a high Institute priority which led, in October 1985, to the establishment of an extramural branch focused on such disorders. Activity will seek to increase knowledge about disorders like adolescent depression and will include treatment research and support for research training.

- The Institute has been increasingly active in dealing with the critical need to understand the growing problem of youth suicide. There is research under way, and currently starting, that studies this problem; attention is being directed to suicide completers and suicide attempters. There is also intramural research work on biological aspects of youth suicide. In addition, Dr. Frazier, the Institute Director, is chairing the Department's Task Force on Youth Suicide which is taking a comprehensive look at the problem and ways to address it. The Institute is working closely with the Centers for Disease Control regarding youth suicide.

- NIMH is continuing it's research interest in child abuse through support of projects aimed at learning more about the occurence of child abuse and about ways to head it off. The Institute collaborates in this area with the National Center on Child Abuse and Neglect and with the Office for Victims of Crime (Dept. of Justice).

CLINICAL TRAINING

Question. The Senate report accompanying the FY 1986 Appropriations Bill "direct(ed) NIMH to provide the Committee with a full report by January 1, 1986, on the number of predoctoral and postdoctoral trainees supported with a payback requirement for the past 4 years in each of the mental health disciplines and the percent of each discipline's support that reflects payback funding." The report also directed NIMH to provide the Committee with data on the amount of institutional support received by each of the professions and the purposes for which such support is used.

The Senate called for this report because significant questions have been raised regarding NIMH's allocation of funds between stipend and institutional support. Before considering whether there is a need to mandate greater use of the "payback" mechanism

(which provides that for each year of stipend support a trainee must work for one year in a designated shortage area), the Committee wanted to have before it all of the facts relating to past use of the payback provision as well as descriptions of the purposes for which institutional grants are used (these awards incur no payback obligation).

The payback obligation provides the main rationale for continued support for the clinical training program, which is to train professionals to work in shortage areas and among special populations. This Committee has been asked to consider mandating at least 75 percent of the clinical training funds for stipend support thereby incurring the payback obligation for each of the professions. I would like to ask Dr. Frazier to comment on the status of this report (we understand it has not yet been submitted) and to give his views on the need to limit funding more strictly to stipend support, which directly channels professionals into areas most in need of services.

Answer. The report on Clinical Training and the Payback Obligation requested by the Senate Appropriations Committee has been completed by NIMH and was sent February 27, 1986.

The proposed budget request terminates Federal funding for mental health clinical training programs. However, if funding were to continue, I would strongly oppose limiting clinical training funding largely to stipend support. The relative emphasis on teaching (institutional) or student support in NIMH clinical training varies with the program and the discipline being supported. In programs with a strong research and development focus, such as the new prevention initiatiave, funds are needed for curriculum development, materials, and teaching, rather than for students. The same is true of many of our grants for training in geriatric mental health. In State Human Resources Development grants, all funds are for nontrainee costs, such as personnel, data, equipment, or travel, and any training which is done is generally short-term to nonstipended students.

Nonmedical disciplinary training in established programs, especially in psychology, stresses student support. Faculty have guaranteed salaries, funded by the universities and student tuition, and stipends for trainees, who have few other sources of support, are the primary need. In contrast, psychiatry and other medical school faculty are expected to generate income to pay for their salaries through provision of clinical services or through research or training grants. If the grant does not pay the salary, faculty time is spent in seeing patients, not in teaching, and new curricula are not developed and new or priority content is not stressed. Unlike trainees in the nonmedical disciplines, psychiatry residents, since they are fully licensed physicians, generate enough income from fees-for service to cover their stipends (with no payback requirement) and thus have no incentive to take NIMH stipends. Quite simply, if emphasis on priority areas is to be incorporated in psychiatry curricula, it must be done through the provision of teaching costs. Psychiatric nursing has many similar needs for funds to cover faculty salaries, although not to such a great extent as psychiatry.

It is unfortunate that this difference in the funding needs of the disciplines, which is not connected with the payback requirement, is seen as resulting from it. In fact, data from earlier studies show that trainees in all the disciplines tend to take jobs after completion of training which are in the public sector and which would probably fulfill the payback requirement. The move to private practice, which is attractive to many psychologists, psychiatrists, and social workers, usually takes place several years after the completion of training, and after any potential payback obligation.

NIMH has completely reoriented its clinical training program to focus exclusively on the needs of underserved population groups: children, the elderly, the chronically mentally ill and minorities. In addition, research and demonstration initiatives in these areas and on prevention, and the State human resources development program, try in different ways to prepare service providers to serve the public. Grants stress both teaching and student support to achieve these aims, and both are necessary for a comprehensive and inclusive program. The payback provision is but one of many ways to reach the goal of service to all segments of society.

Question. Two of the three clinical training grant announcements just released for FY 1986 provided unworkably short turnaround times, two weeks in one case and three weeks in the other. Would Dr. Frazier explain to the Committee why the grant announcements were released with such short response times and what measures will be taken to insure more timely notice in FY 1987.

Answer. They very short turnaround time for some of the clinical training announcements was an unfortunate result of the budget and review cycle. No funds were requested for clinical training in that year, and the initial marks of the House and Senate were quite divergent. The House recommended $8,000,000, or very little beyond that necessary for noncompeting continuation awards. The Senate recommended $24,000,000. Both bodies provided a list of priorities. It was not until October 1985 that NIMH was aware of the size of the appropriation and the various directives associated with it. It was only then that we could plan tentative allocations and begin to write an announcement in accord with these. We made the receipt date for applications as late as possible, consistent with the work load at the Division of Research Grants at NIH, which handles all applications. A special session of the National Advisory Mental health Council will be held in June for final review, so grants can be awarded with start dates of July or September, 1986.

We will try to assure a more timely notice to the field in FY 1987 if there is a clinical training program. However, we will still be unable to write or mail an announcement in this area until we have definite knowledge of the size of any possible program and the recommendations or directives of both Houses of Congress which would influence the nature of the announcement.

AIDS

Question. The Committee was delighted to learn of the current availability of $500,000 in NIMH support for research on the mental health aspects of AIDS, which includes attention to the neuropsychological, behavioral and psychosocial aspects of AIDS, changes in high-risk sexual behavior and effects on certain high-risk minority populations. What are your plans to fund additional AIDS-related initiatives in the following critical areas: (1) provision of psychological treatment for AIDS patients and their families; (2) training and services for mental health professionals who treat AIDS patients; (3) public education regarding transmission of AIDS; and (4) information dissemination of AIDS-related research findings and implications?

Answer: NIMH will not directly provide support for treatment for AIDS patients through extramural research grant funds. However, through the AIDS Research Centers, specific funds may be requested as part of the research plan to cover patient costs.

NIMH will issue a Request for Announcement for training of Mental Health professionals entitled, "Training for Health Care Providers to Address Acquired Immune Deficiency Syndrome (AIDS)".

The AIDS Research Centers also include an information dissemination component. The goal is to provide rapid dissemination to the clinical community as well as to the research community.

MENTAL HEALTH SERVICES REIMBURSEMENT

Question. The Committee knows that NIMH is the central federal agency for attention to issues regarding mental health services. We are especially interested in your work related to policy research. Other agencies have deferred to NIMH for research and analysis that is essential for sound policy recommendations regarding mental health. We are aware, for example, of the superb work being done examining the possible expansion of the Medicare prospective payment system to psychiatric specialty settings. Your work is generating an impressive amount of empirical evidence to guide Congress and the Federal government on policy decisions in this area. This work is essential to assure the future delivery of mental health services to all our nation's citizens. We are very appreciative of your efforts in this area.

The Committee strongly believes that this new line of policy research related to mental health services and reimbursement affects the future of mental health as a science and discipline. We recognize the importance of developing both a research capacity and support for specific project. How are you focusing attention on this work in NIMH? Are you encountering any problems in generating necessary attention and support, and is there anything this Committee can do to help?

Answer. The National Institute of Mental Health has established a Mental Health Service System and Health Economics Research Program in the Division of Biometry and Applied Sciences,

with support for grant and intramural research, as well as research training in these areas.

The desire of the Committee to be of help is greatly appreciated. However, our main problem in this area is the relatively small number of field-initiated research grant applications relating to mental health economics. We have attempted to get around this problem by supporting a significant proportion of research through the use of contracts. This has been particularly true with respect to work on the Medicare Prospective Payment System for psychiatric patients. Thus, our most pressing task at the present time is to continue to provide leadership and stimulate good multidisciplinary, investigator-initiated grant research.

ST. ELIZABETHS HOSPITAL

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

D.C. SUPPORT OF ST. ELIZABETHS HOSPITAL

Question. Has the District Government been able to increase its support for St. Elizabeths Hospital in accordance with the provisions of Public Law 98-621 and the Administration's Budget schedu e?

Answer. The District Government has increased its support for St. Elizabeths Hospital in accordance with Public Law 98-621. In FY 1984, the District of Columbia payment for support of Saint Elizabeths Hospital was $35,149,000. A shortfall does however exist for both FY 1986 and FY 1987. In FY 1986, the District Government has included $62,970,000 in its budget for payment to St. Elizabeths Hospital while our appropriation authorizes $65,377,000. The Federal estimate for District support in FY 1987 is $76,798,000; the District has included $71,200,000 in its FY 1987 budget submission, thus creating a potential budget shortfall of $5.6 million. These shortfalls exist primarily because both the Federal and District shares for the FY 1986 budgets were originally projected on the basis of the President's proposed across-the-board 5 percent pay cut. Even though the pay cut was not implemented, the amounts included in the FY 1987 Federal appropriation request and the District's payment projection remained unchanged.

Question. What is the District's current level of support for the Hospital?

Answer. In FY 1986, the District of Columbia Government has budgeted $62,970,000 for support of St. Elizabeths Hospital. Of this amount $1,070,000 has been sequestered pursuant to the Gramm-Rudman-Hollings legislation.

PATIENT DEATH

Question. You can imagine my reaction when I learned that Mr. Emery Lee had died on January 18 of this year while in seclusion at St. Elizabeths Hospital. At my request, the District of Columbia Protection and Advocacy Agency explored the circumstances of Mr. Lee's death, and the Health Care Financing Administration came to the Hospital to investigate the death. I also understand that the District Delegate, Walter Fauntroy, is conducting an investigation into Mr. Lee's death. What are the findings of your Hospital's investigation into Mr. Lee's death?

Answer. The Hospital's Utilization Review Committee is undertaking an exhaustive examination of the circumstances of Mr. Emory Lee's tragic death. This inquiry includes a review of the appropriateness of his admission, the environment in which he was treated, the supervision and training of staff involved, the seclusion policies, the medical care received, and will incorporate findings from the District of Columbia Medical Examiner. Although District officials held a press conference on March 13, 1986, a written report from the Medical Examiner has not been received. The District's press conference revealed Mr. Lee's death was due to natural causes, complicated by a heart problem, mental retardation, Down's Syndrome and obesity. Nevertheless, we are quite concerned about his treatment. Although not the cause of his death, we want to provide appropriate therapeutic care for all patients. The committee will shortly be presenting its findings and recommendations to the Hospital Superintendent. The Superintendent will then release to the public a statement on his conclusion.

Question. Has the Health Care Financing Administration reported to you on its findings?

Answer. Although Saint Elizabeths has not yet received a written report from HCFA on its findings, the HCFA site team reported at the exit conference that they had found no improper staff actions concerning care provided Mr. Emory Lee, nor in the circumstances of his death.

Question. What is St. Elizabeths doing to prevent any such tragedy from occurring again in the future?

Answer. Saint Elizabeths Hospital has taken several actions to prevent or better manage any similar future incidents. In addition to conducting its own internal review of exactly what happened, Saint Elizabeths Hospital staff have cooperated and are cooperating with an investigation by the District of Columbia Police Department, with a review by the Health Care Financing Administration, and with a review of the incident being conducted by the staff of the House Committee of the District of Columbia. Special attention is being given to this last review by Delegate Walter E. Fauntroy and the Sub-Committee on Fiscal Affairs and Health which he chairs.

In addition to these reviews, Saint Elizabeths has taken further steps to assure that at all times there is a sufficient number of appropriately trained staff providing inpatient services throughout the hospital, with special attention to the staffing in the area where Mr. Lee died. Some registered nurses who work in that division of the hospital and who previously have been assigned to outpatient duties only are working on inpatient shifts as well. Even though excessive heat was not determined as the cause of death, clinical staff on those wards have also been instructed to carefully monitor patients during times when the weather becomes warm and to immediately notify Engineering if it is necessary for the heat to be cut back or turned off. Engineering staff are also assisting with monitoring the heat in buildings to assure that safe levels are maintained.

STATUS OF TRANSFER

Question. What is the status of the plan for transferring the management of St. Elizabeths Hospital to the District of Columbia and the development of a comprehensive mental health services system for District residents?

Answer. Much has been accomplished in preparation for transfer:

- A Preliminary System Implementation Plan has been completed by the Mayor's Mental Health Systems Reorganization Office and has been submitted to the District of Columbia City Council for review. This plan describes a comprehensive approach to the delivery of community based public mental health services to all residents of the District of Columbia. It contemplates reasonable reductions in the chronic long term adult inpatient population of Saint Elizabeths Hospital and substantial increases in program support in the areas of adult ambulatory care, child and adolescent services and forensic psychiatric services. Over 150 Saint Elizabeths Hospital staff participated in the development of this comprehensive plan.

- Preliminary draft staffing patterns have been developed for each of the service components described in the Preliminary System Implementation Plan. These staffing patterns have been distributed to all interested parties within the system for analysis and review.

- Detailed analyses of the physical facilities located on the campus of Saint Elizabeths Hospital have been completed. These analyses include a full physical plant audit mandated by the Act and the report of a consultant to the Mental Health Systems Reorganization Office. The framework for site planning and development of alternative

strategies for physical plant utilization have now been laid.

- An audit of the financial statements of Saint Elizabeths Hospital has been completed pursuant to the requirements of the Act. The results of the audit were the issuance of a unqualified opinion that the financial statements fairly represent the financial position of the Hospital and that no material weaknesses were identified in the internal control practices of the Hospital.

- The Mayor has created a Reorganization Implementation Team and charged it with the responsibility for finalizing transition plans and implementing the System Implementation Plan. This team, made up of high ranking officials of the District of Columbia Department of Human Services, Saint Elizabeths Hospital, and the Department of Health and Human Services has already begun the process of transition which will allow uninterrupted delivery of quality services during this important transition period.

In FY 1987, our goals and objectives are directed primarily at completion of preparations for transfer. Specifically we hope to accomplish the following:

- Functional reorganization of Hospital inpatient programs to achieve alignment with the System Implementation Plan.

- Transfer of outpatient treatment responsibility from Hospital-based programs to existing community mental health centers, with appropriate reassignment of clinical staff to these centers.

- Completion of analysis of physical plant requirements to assure consistency with the District's physical plant utilization plan and redirection of remaining capital improvement resources to renovations required under the Plan.

- Completion of all necessary changes to the Preliminary System Implementation Plan consistent with the timetable contained in the legislation.

- Finalization of program staffing patterns preparatory to the transfer of employees to District government management on October 1, 1987.

Question. Are preparations proceeding according to the schedule mandated in Public Law 98-621?

Answer. Yes, the preliminary system implementation plan has been developed, reviewed by the Council of the District of Columbia and I understand, will be forwarded to the Congress as required by P.L. 98-612.

Question. Do you foresee any stumbling blocks to accomplishment of the transfer on October 1, 1987?

Answer. There are four major areas in which there remain issues to be settled. Progress is being made in all of them.

The first area concerns use of the property at Saint Elizabeths which will not be used for District of Columbia Mental Health Services. The plan in its first draft does not provide detail on this topic but will in its next draft which will be available in the fall of this year. A request for additional detail on the property was also one of the items which came out of the action by the Council of the District of Columbia and by groups testifying at the public hearings. There is considerable concern and opposition to locating a prison on the site.

The second area in which decisions have yet to be made is the additional Federal financial responsibility primarily for capital improvements to comply with applicable code requirements of facilities to be used by the District; and funding for ongoing training programs. It is my understanding that the District's estimate for additional capital improvements funds is in excess of $40 million. Based on the physical plant audit we have begun work to develop a Fiscal Year 1988 budget request for construction and renovation in compliance with code. We anticipate intensive negotiations with District officials concerning capital improvements.

The third and perhaps broadest area is the question of how successfully Saint Elizabeths Hospital and the District of Columbia will be able to implement the plan. Preliminary implementation efforts are already underway in order to take advantage of the provision of Public Law 98-621 which allows transfer of responsibility for selected programs from Saint Elizabeths to the District of Columbia prior to October 1, 1987. Saint Elizabeths Hospital is beginning internal reorganizations in order to align its programs with those planned for the future system and to make the transition easier.

The fourth major area in which implementation will be difficult is that of outplacement of several hundred current Saint Elizabeths patients into community facilities and nursing homes. The Hospital's realignment will make it easy to identify these patients. Joint efforts with the District of Columbia are underway to assure that appropriate clinical placement of these patients begins to occur quickly.

IMPROVEMENTS TO HOSPITAL ADMINISTRATION

Question. What improvements have St. Elizabeths Hospital administrators made over the past year in cost control, management of services delivered, and financial management practices?

Answer. The Hospital has made the following improvements:

- o Internal accounting and financial management practices have been improved, resulting in an ability to produce financial statements consistent with generally accepted accounting principals. The Hospital was audited by an independent accounting firm and received an unqualified opinion that its financial statements fairly represent the financial position of the Hospital and that no material weaknesses in internal control practices were identified.

- o Cost accounting practices have been improved through automation and more sophisticated production of cost reports acceptable to the Health Care Financing Administration and the District of Columbia Office of Health Care Financing.

- o Increased automation in billing, collections, and accounts payable led to a fifteen percent (15%) reduction in administrative staff ceilings, while improving the overall efficiency of the organization.

- o Improved monitoring and tracking capabilities in the Hospital's Budget and Fiscal Accounting Units have permitted greater regulation of expenditures in non-personnel areas. Spending in the clinical programs has been linked to standards for the services being rendered.

- o With the completion of the Hospital's automated Billing and Accounts Receivable Management System, more timely billing and collections activities have occurred in the current fiscal year and have permitted more accurate projections of future fiscal year revenues.

- o Procurement practices have been improved, resulting in bulk purchases at lower prices and full exploitation of purchasing authority through other Federal agencies, particularly the Department of Defense.

Question. How much have these improvements helped to increase independent revenues at the Hospital?

Answer. Changes in the methodology used to prepare the annual cost report will directly increase revenues by approximately $1.3 million beginning in FY 1986. Improved collections practices will result in increased payments and more timely payment from commercial and private payers. While actual collections still lag behind delivery of services, the Hospital now projects total revenues in prior fiscal years which exceed the amounts obligated for Hospital costs. Specifically, in FY 1983 the Hospital projects a

return to the Treasury of approximately $3.0 million in excess revenues. In FY 1984 and FY 1985, the amount will approach $2.0 million for each year. In FY 1986, Gramm-Rudman sequestration will result in the Hospital turning back cash receipts of approximately $2 million collected above current spending authority.

DEINSTITUTIONALIZATION

Question. What progress has the Hospital made in removing inpatients at St. Elizabeths to more appropriate accommodations in the community?

Answer. Saint Elizabeths Hospital continues to seek ways to maintain and improve, when possible, the quality of programs involving the deinstitutionalization of patients from the hospital. The Hospital's clinical divisions emphasize specialized psychiatric rehabilitative care services and programs. A primary goal is the preparation of patients for outplacement, through one to one therapy, group or family therapy and progression from one program to another program which requires more activity of daily living skills. Patients evaluated to be long term are reviewed by a treatment team at least quarterly. Each treatment plan includes a statement regarding outplacement plans.

One program at SEH related specifically to deinstitutionalization is the Positive Reinforcement Outplacement Program (PROP) which involves the training of Community Residential Facility operators in dealing with hard-to-place patients. Another program in place involves the Section 8 specially designated rental certificates which are used by our mental health system patients. One recent program developed with the Mental Health Services Administration and a community-based agency resulted in the placement of inpatients into the community, all who previously experienced several failures with community living. This particular program has been extremely successful. Contracting by the Hospital with several community-based agencies provide socialization services, transitional living services and transitional employment services for hospital patients. During March 1985, the hospital approved and put into operation a program which provides up-front money for room and board, with specific guidelines for use by the hospital patients. This program will assist staff in helping patients return to the community without waiting from one to two months for the required finances.

Special nursing care and regular nursing care placements are not developing as rapidly as desirable. Nursing care beds for special placement are not completed and the accessibility of regular nursing care beds is limited because the number of potential users exceed the number of available beds. Several options to access the regular care nursing beds are under consideration.

A comprehensive mental health program which emphasize a community-based system has been developed in accordance with Public Law 98-621. A Preliminary System Plan has been developed and forwarded in compliance with Public Law 98-621. In the Plan, deinstitutionalization of patients from Saint Elizabeths Hospital will continue. Continuity of care is emphasized and safeguarded.

SUBCOMMITTEE RECESS

Senator HARKIN. The subcommittee will stand in recess until Tuesday, March 18, at 9:30 a.m., and we will meet in Dirksen 116, and at that time we will have testimony from the Health Care Financing Administration, the Social Security Administration, the Office of Refugees, and the Office of Child Support Enforcement.

[Whereupon, at 11:58 a.m., Thursday, March 13, the subcommittee was recessed, to reconvene at 9:30 a.m., Tuesday, March 18.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1987

TUESDAY, MARCH 18, 1986

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:30 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker, Specter, Proxmire, and Chiles.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH CARE FINANCING ADMINISTRATION

STATEMENT OF HENRY DESMARAIS, ACTING ADMINISTRATOR

ACCOMPANIED BY:

DENNIS WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

CHRISTOPHER GAMBLE, DIRECTOR, DIVISION OF BUDGET

INTRODUCTION OF ASSOCIATES

Senator WEICKER. The hearing will come to order. This morning, we will hear testimony from Dr. Henry Desmarais, the Acting Administrator of the Health Care Financing Administration [HCFA] which has jurisdiction over the Medicaid and Medicare Programs.

We look forward to your testimony. Please introduce your colleagues, Dr. Desmarais, and proceed in any way you deem fit.

Dr. DESMARAIS. Thank you, Mr. Chairman.

With me this morning to my left is Mr. Dennis Williams, the Department's Deputy Assistant Secretary for Budget, and to my right is Christopher Gamble, the Director of HCFA's Division of Budget.

HIGHLIGHTS OF FISCAL YEAR 1987 BUDGET REQUEST

I intend to briefly summarize my testimony, and I would ask that the full statement be entered into the record.

The President's fiscal year 1987 budget reflects the administration's continued commitment to restraining health care costs in order to do our part to reduce the deficit and maintain the solvency of the Medicare trust funds. The President's budget includes a number of regulatory and legislative initiatives, which would reduce our share of the Federal health care expenditures by $5.4 billion in fiscal year 1987, and by a total of $55.4 billion over the next 5 years. I would like to briefly summarize the appropriations request.

MEDICAID

The fiscal year 1987 request for grants to States for Medicaid is $24.7 billion. This request reflects legislative proposals that would limit the growth in the Federal expenditures for Medicaid through a cap and eliminate special matching rates for various administrative expenses incurred by the States.

PAYMENTS TO THE HEALTH CARE TRUST FUNDS

The fiscal year 1987 request for payments to the health care trust funds is $20.4 billion. This request reflects an increase of 8 percent over the comparable fiscal year 1986 level. The enactment of several legislative proposals, particularly the change in the part B premium so that over time it would account for 35 percent of the cost of the part B program, would allow our appropriation request to be reduced by $1.3 billion in fiscal year 1987.

PROGRAM MANAGEMENT

The fiscal year 1987 request for program management is $1.3 billion, which is distributed across the following activities:

RESEARCH

The fiscal year 1987 request for research is $18.5 million. This request reflects the continuation of high-priority projects, including a variety of congressionally mandated studies.

MEDICARE CONTRACTORS

The fiscal year 1987 request for the Medicare contractors is $957 million, with an additional $50 million for a contingency fund.

SURVEY AND CERTIFICATION (MEDICARE)

The fiscal year 1987 request for Medicare survey and certification activities is $57 million. This request reflects an increase of 15.2 percent over the fiscal year 1986 level.

END-STAGE RENAL DISEASE NETWORK COORDINATING COUNCILS

We are requesting only $1 million for the councils in fiscal year 1987. This request assumes the implementation of a regulatory proposal to reduce the total number of councils to a minimum. In addition, the administration has submitted a legislative proposal to eliminate the councils. This proposal reflects our belief that the councils are inefficient and duplicative.

ADMINISTRATIVE COSTS

The fiscal year 1987 request for administrative costs is $215.2 million. This request reflects a staffing reduction of 143 full-time equivalents through attrition and streamlining of the administrative process.

GRAMM-RUDMAN-HOLLINGS

Before closing, I would like to make a brief mention of the impact of the Gramm-Rudman-Hollings provisions. The triggering in fiscal year 1986 of Gramm-Rudman-Hollings has required a reduction of $54.4 million in program management. Most of this reduction, that is, $41.4 million, occurs in the Medicare contractor budget activity. Its impact will be a gradual increase in the number of days of work on hand. It will, therefore, take somewhat longer for Medicare claims to be paid.

PREPARED STATEMENT

This concludes my prepared remarks, Mr. Chairman. I am available for questions at this point.

[The statement follows:]

STATEMENT OF HENRY DESMARAIS

Mr. Chairman and Members of the Subcommittee, I am pleased to be with you today to present our FY 1987 budget request for the Health Care Financing Administration (HCFA). This budget plays a prominent part in delivering affordable and top quality health care to the 52 million elderly, disabled and poor who depend upon programs like Medicare and Medicaid. While our function centers on the compassionate delivery of needed health care, we try to assure that such care is provided efficiently.

Before I focus on specific appropriation items of interest to this Subcommittee, I will briefly mention our approach in developing these budget request proposals. When this Administration took office, Medicare health care costs were rising at 21 percent a year. For the current fiscal year, this increase is estimated to slow to 5 percent. This decrease has been accomplished through reforms that have maintained access to quality care by a growing number of beneficiaries. The prospective payment system (PPS) for hospital reimbursement has been a prominent factor in slowing the rate of benefit expenditures through incentives for providers to promote more efficient practices.

Overview

Our 1987 budget reflects the Administration's continued commitment to restrain health care costs in order to do our part to reduce the deficit and sustain the solvency of the Medicare trust funds. In order to accomplish this goal, this budget proposes a number of regulatory and legislative initiatives designed to hold down expenditures. The projected 1987 expenditures for Medicare and Medicaid represent an increase of only $1.6 billion above the current 1986 estimate, or 1.7 percent.

Savings Initiatives

In Medicare, these savings focus on areas that are overpriced or poorly controlled. Hospital reimbursement proposals generally either constrain current cost-based items outside the prospective payment system to inflation levels in the overall economy or integrate the payments into that system. Physician payment limits are held to levels more representative of cost increases directly affecting their profession and overpriced items are reduced to realistic levels. In Medicaid, we propose to continue building on successful approaches adopted over the last several years to deliver care more efficiently and at lower cost.

Together these proposals will reduce our share of Federal health care expenditures by $5.4 billion in 1987 and by $55.4 billion over the next 5 years.

I would now like to review briefly our appropriations request.

Grants to States for Medicaid

The Medicaid program provides grant funding to all States and the territories for medical care for approximately 23 million low income persons. Our FY 1987 request of $24.7 billion reflects the following legislative proposals:

1) to limit FY 1987 Federal expenditures for medical assistance payments (other than Puerto Rico and the territories) to $23.3 billion and to constrain future years' growth to the Medical Care Price Index; and

2) to reform Federal payments for administrative costs by eliminating special matching rates and by providing incentives for high cost States to improve efficiency.

Our budget request seeks to stem the rate of program growth by encouraging States to pursue alternative ways of financing and delivering health care. To facilitate the implementation of such efforts, the Administration will propose a number of measures to give States additional program flexibility. States will be able to use enhanced authority to target services, organize cost-effective systems of care, and explore innovative ways to finance the delivery of care. In addition, a hardship pool of $300 million will be available in FY 1987 to provide relief to those States which, despite aggressive cost containment efforts, experience uncontrollable increases beyond their funding limit.

Payments to the Health Care Trust Funds

The payments account contains monies appropriated to the Medicare Trust Funds. Federal matching funds supporting the Supplementary Medical Insurance program make up the bulk of this account. In addition, the account includes funds to support benefits under the Hospital Insurance program for those beneficiaries grandfathered into entitlement, and military service credit payments enacted by the Social Security Amendments of 1983.

Our FY 1987 request for this account is $20.4 billion - an increase of $1.5 billion or 8.0 percent. It is composed of the following elements:

- Federal payment for Supplementary Medical Insurance (SMI) -$19.8 billion;
- Hospital Insurance for the Uninsured - $435.0 million;
- Military Service Credits - $94.0 million; and
- Hospital Insurance for Uninsured Federal Annuitants - $12.0 million.

One of our legislative proposals would gradually increase the proportion of estimated expenses covered by the SMI premium revenues to 35 percent by 1991. This proposal, if enacted, could reduce our appropriation request by $1.3 billion for FY 1987, while representing only a small increase per beneficiary.

Program Management

This account provides funding for management activities related to Medicare and Medicaid. The total FY 1987 request of $1.3 billion is broken down into $84.5 million appropriated from general funds, and $1.2 billion authorized to be transferred from the Medicare trust funds. Overall, we have worked to reduce ongoing operating costs and to shift resources to enhance the recovery of trust fund dollars and to develop new information as a basis for future reforms of the system.

The FY 1986 budget for Program Management includes proposed rescissions or deferrals of $9.4 million. Of this amount, $7.3 million has been taken from the Research, Demonstrations and Evaluation budget, and $2.1 million from the Medicare Contractors.

The Program Management request for FY 1987 covers the following program activities:

1. **Research**

   Results gained from research, demonstrations and evaluations produce knowledge about ways to more effectively manage the Medicare and Medicaid programs. Previous investments in this area have produced information critical to the development of legislation and program changes such as the prospective payment system and expansion of health maintenance organizations. We are requesting $18.5 million for research in FY 1987. This budget reflects the Administration's commitment to improve targeting of limited Federal research resources and reflects continuation of high priority projects, including congressionally mandated studies, that require Federal funding in FY 1987.

2. **Medicare Contractors**

   This budget activity provides funding for operating costs incurred by our contractors in administering the Medicare program. Key functions for which Medicare contractors are responsible are claims processing, payment safeguards and service to Medicare beneficiaries. We are requesting $957 million for this budget activity in FY 1987. This amount represents approximately 1.3 percent of Medicare benefits paid by contractors. In addition, a contingency fund of $50 million is requested to cover unanticipated workload

and operating costs which may result from legislative, regulatory and programmatic changes.

The FY 1987 budget reflects a continued emphasis on strengthening payment safeguards, including audit and medical review activities. In FY 1987, HCFA again will focus on reviews to detect unnecessary and inappropriate services provided in hospital outpatient departments, home health agencies, skilled nursing facilities, and by other providers. Medical review and audit activities are expected to result in savings to the program of $989 million in 1987. The budget also reflects the continuation of the Medicare secondary payer efforts by contractors to ensure appropriate payment by third parties where they are primary payer. This program is expected to save about $770 million in Medicare program dollars in 1987 by ensuring that Medicare pays for only those services not covered by private insurance. Total payment safeguard savings are estimated at $1.8 billion in FY 1987.

3. **State Certification (Medicare)**

The State Certification program is responsible for ensuring that both institutional and noninstitutional providers and suppliers rendering health care services to Medicare patients meet acceptable quality and safety standards. Annual agreements are negotiated with State Agencies to perform surveys of health care facilities in accordance with explicit criteria.

The FY 1987 request for Medicare certification activities and program support services is $57.0 million, an increase of 15.2 percent over the FY 1986 program level. This is in addition to the resources required for Medicaid survey and certification which are included in the Grants to States for Medicaid appropriation request. Our FY 1987 request provides for overall survey coverage of approximately 66 percent of the providers and suppliers participating in Medicare. Within that total level of funding, we will continue to survey 100 percent of long term care facilities. The requested level will provide an increased coverage for hospitals from 50 percent to 75 percent. The survey of home health agencies will be expanded to include approximately 6,400 actual visits to the home. Additionally, 100 percent survey of psychiatric hospitals for staffing and medical records is requested for FY 1987.

4. **End-Stage Renal Disease (ESRD) Network Coordinating Councils**

ESRD Network Coordinating Councils are responsible for reviewing quality of care and efficient utilization of

resources devoted to kidney dialysis and transplantation services. However, these Councils have not proven effective.

Therefore, we are developing a regulation that will allow us to administratively reduce the number of Councils and Networks from 32 to a minimum number, possibly 2. The FY 1987 request of $1 million will support this minimum number of Councils. At the same time, we are submitting a legislative proposal to eliminate the requirement to maintain these Councils.

5. **Administrative Costs**

The Administrative Costs budget activity provides the necessary operating funds to enable HCFA to carry out its program responsibilities. These responsibilities include managing the Medicare and Medicaid programs, coordinating Federal survey and certification efforts, and directing a variety of activities to assure high quality health care.

HCFA staff is continually working toward improving the delivery of health care services provided through the Agency's programs. In FY 1987, HCFA staff will continue to build on initiatives to:

(1) reduce unnecessary regulatory and administrative burdens;

(2) promote competition in the health care industry;

(3) implement Medicare program modifications designed to improve the quality of care; and

(4) reduce program costs.

The FY 1987 budget request is $215.2 million. This level is essentially level with the FY 1986 appropriation. This budget request is consistent with the government-wide effort to achieve administrative efficiencies and reduce the deficit in FY 1987. Savings will be realized through staff attrition and streamlining administrative processes and requirements.

The FY 1987 request will fund a staffing level of 3,757 full-time equivalents (FTEs). This is a reduction of 143 FTEs from our authorized ceiling in FY 1986. HCFA will reduce staffing resources through attrition, thus resulting in no adverse impact on HCFA staff. We are confident that the reduction will be accomplished without a disruption to HCFA's programs.

Gramm-Rudman-Hollings

The Gramm-Rudman-Hollings legislation requires that $54.4 million of administrative expenses be withheld from obligation in FY 1986. This reduction requires:

- A reduction of $1.3 million in research which will defer new awards for studies of benefit coverage issues, and new studies of the efficacy of preventive services and patient education efforts.

- The primary impact of the reduction of $41.4 million in the Medicare Contractors activity is to increase the days work on hand from 9 days to 16 days for Part A, and from 11 days to 18 days for Part B. In addition, the contingency fund will be reduced by $.6 million.

- A reduction of $2.2 million for the State Certification activity will require reduced survey coverage for non long-term care facilities that traditionally have experienced few deficiency problems. These include Home Health Agencies, End-Stage Renal Disease facilities and laboratories. A total of 890 surveys will be deferred.

- A reduction of $0.2 million in the ESRD Network Coordinating Councils' activity will have a minimal impact on travel, consultants and other overhead.

- A reduction of $9.3 million in Administrative Costs means that the Agency will be unable to fund 19 full-time equivalents within the approved ceiling, will eliminate selected management support contracts, and will reduce funding for such activities as travel and training by about 25 percent. Although these reductions result in a reduced level of operations, HCFA will not furlough employees.

This concludes my remarks, Mr. Chairman. I will be happy to answer any questions the Subcommittee may have.

57-852 O—86——31

FORMULATION OF FISCAL YEAR 1987 BUDGET REQUEST

Senator WEICKER. What was the Health Care Financing Administration's original fiscal year 1987 budget request to the Department?

Dr. DESMARAIS. Mr. Chairman, are you referring to the HCFA submission to the Department in all of the categories, or some particular categories?

Senator WEICKER. Overall.

Dr. DESMARAIS. The HCFA request to the Department, and I distinguish that from the Department's request to the OMB, was as follows: for research, $33 million; for the Medicare contractors, $1.017 billion, with a contingency fund of $38.7 million; for survey and certification, $60 million; for the ESRD network coordinating councils, no funding, reflecting a legislative proposal to eliminate the councils; for administrative costs, $224 million.

Senator WEICKER. And the Department's request to OMB?

Dr. DESMARAIS. The Department's request to OMB was somewhat different; for research, $22.9 million; for the Medicare contractors, $995.5 million, including a contingency fund of $20 million; for survey and certification, $57 million; for the ESRD network coordinating councils, $4.8 million, reflecting current services; for administrative costs, $222.6 million.

PROPOSED MEDICAID CAP

Senator WEICKER. Do you want to discuss the situation with Medicaid? You propose to cap Medicaid dollars at $1.2 billion less.

Dr. DESMARAIS. It is a reduction of $1.3 billion, with a $300 million one-time special fund to help in the transition to the cap.

Senator WEICKER. Senator Proxmire.

MANDATORY SECOND SURGICAL OPINIONS

Senator PROXMIRE. Thank you, Mr. Chairman.

How do you pronounce your name?

Dr. DESMARAIS. De-mare-is.

Senator PROXMIRE. Not Day-mar-ay.

Dr. DESMARAIS. It is Day-mar-ay in French, but for purposes of this hearing, we will confine ourselves to De-mare-is. [General laughter.]

Senator PROXMIRE. Spoken like a true son of New Hampshire.

Senator WEICKER. He also appeared before the only U.S. Senator who was born in Paris, France.

Senator PROXMIRE. You were born in Paris?

Senator WEICKER. Yes.

Senator PROXMIRE. You can't be President.

Senator WEICKER. That is right.

Senator PROXMIRE. What a shame.

Senator WEICKER. For other reasons, I might add.

Senator PROXMIRE. You are one of the few people I know who could be nominated by both parties. [General laughter.]

Dr. Desmarais, does HCFA support the concept of requiring mandatory second surgical opinions for Medicare recipients in the case of certain procedures?

Dr. DESMARAIS. No, sir; we don't support a mandatory second surgical opinion program for Medicare, although, as you know, in this year's budget, there is a proposal for a mandatory second surgical opinion program for Medicaid. The Medicaid proposal is predicated on research done by Abt Associates for us. There has been no good research done, however, on whether a mandatory second surgical opinion program for Medicare would be of use. I should also note that the peer review organizations are already addressing the issue of inappropriate or unnecessary inpatient surgeries.

Senator PROXMIRE. Last year, in a response for the record, regarding the three or four recommendations made by the Inspector General's Office over the past 2 years that would produce the greatest savings if HCFA agreed to implement them, the inspector general listed second surgical opinions as one of the three most significant money-saving options.

The inspector general estimated that you could save $65 million under the Medicare Program, and $135 million under the Medicaid Program each year if you implemented the second surgical opinion program. The inspector general made it clear in his record response that he did not base his Medicare cost-saving estimates on Medicaid mandatory second opinion programs in certain States, but on a New York Medicare demonstration project which was reported on by Abt Associates.

If the inspector general has concluded that such an approach would save dollars, and obviously avoiding unnecessary surgery would save lives, why don't you request legislative authority to implement a mandatory second surgical opinion program?

Dr. DESMARAIS. We have discussed the issue of mandating the use of second opinions in Medicare, but we disagree with the inspector general's recommendation in this area. In part, the research that you refer to really predates the implementation of the peer review organizations. We believe that the peer review organizations probably have the same kind of sentinel effect with respect to unnecessary admissions and unnecessary surgery.

Certainly, the inspector general has called very strongly for this particular recommendation, and has discussed it with a number of committees in the Congress. But up until now, the administration and the Department have not been persuaded that a mandatory second surgical opinion program in Medicare would be effective.

Senator PROXMIRE. Do you expect to consider the issue further?

Dr. DESMARAIS. We will consider it further. This year's budget does include a provision for mandatory second opinions in Medicaid, which is part of the inspector general's recommendations in this area.

Senator PROXMIRE. It is part of it, that is right, but he referred to Medicare, too.

CORNELL MEDICAL CENTER SURVEY

Doctor, a record response to a question I submitted to HCFA last year frankly puzzled and dismayed me. I asked about a Cornell Medical Center survey that found 14 percent of recommendations for elective surgery were not confirmed when patients asked for second opinions. I read about the survey in a newspaper article.

The response was that the work was presumably done by Dr. Eugene McCarthy but, to the best of your knowledge, Dr. McCarthy did not share the results of this research with you. Does your office ignore research in this most important area unless the individual researcher takes the time to share the research with you?

Don't you feel that HCFA has a responsibility to keep abreast of developments in this field?

Dr. DESMARAIS. We try to keep abreast of relevant research. I am not familiar with the particular study you cite here.

Senator PROXMIRE. Will you check into this survey and let us know what you think of it for the record?

Dr. DESMARAIS. I will be happy to submit what we know about it for the record.

[The information follows:]

DR. MCCARTHY'S RESEARCH ON SECOND OPINIONS

In the case of the findings you reference, HCFA's response indicated that until we saw the reports of his findings in the media, we were not aware that Dr. McCarthy had conducted followup studies.

Much of the research done on second opinion programs in recent years has been sponsored by corporations, business coalitions, and private insurers. From HCFA's perspective, these studies have the following limitations: findings are often not published in the open literature; findings have not been peer reviewed, and often results are proprietary. HCFA would have welcomed the opportunity to have taken Dr. McCarthy's more recent research into account as it formulated a position on second opinion programs. Unfortunately, we did not have the kind of collaborative relationship with Dr. McCarthy to facilitate the exchange of this information.

ROUNDING OF PART B PAYMENTS

Senator PROXMIRE. Your inspector general also estimated that Medicare part B could save about $45 million a year if payment for odd-penny claims were rounded, on a per claim basis, to the next lower whole dollar. Do you plan to seek authority to institute such a practice? If not, why not?

Dr. DESMARAIS. The Department considered that particular recommendation when the fiscal year 1987 budget was put together, but decided not to accept it. There are, nevertheless, a number of proposals in the budget that would have an impact on part B expenditures. Certainly that recommendation would not be appropriate for either a prospective payment type of system or for cost limits, so that the applicability would be somewhat narrowed.

Senator PROXMIRE. Are you saying that it would not save $45 million.

Dr. DESMARAIS. No, sir; I am not sure exactly how the estimate was developed. We discussed this particular recommendation, and the De-

partment chose not to include it in the budget request. Of course, we have a number of other provisions that would affect how much we pay for a variety of part B services.

MEDICARE PAYMENT CYCLE

Senator PROXMIRE. Your inspector general has estimated savings of between $320 million and $423 million a year through adherence to a 30-day pay cycle under the Medicare Program. At the present time, payments are made within an average of 10 to 11 days instead of the 30-day cycle, which is standard business practice and which is endorsed in OMB's Circular A-125. Of course, the 30-day cycle avoids loss of interest on the cash balances or higher interest on the national debt.

Are you requiring intermediaries or carriers to apply a 30-day cycle standard to their Medicare payments? If not, why not?

Dr. DESMARAIS. We are not requiring it, but we are certainly moving in that direction. The figure you cite on how fast claims are currently being paid does not reflect the whole picture. Today, on the average, our contractors under part A of Medicare have 9 days of work on hand. This statistic does not include the time it takes for the claim to arrive at the intermediary, nor does it include the time it takes to generate a check, which, on the average, is 3 days once the claim is processed, excluding weekends and holidays. It also does not reflect the time it takes for the actual payment to be mailed and received. Once these additional steps are considered, the payment cycle is considerably lengthened.

Additionally, the inspector general makes reference to the Prompt Payment Act. Our attorneys tell us that we really are not bound by that act. We are, nonetheless, moving in its direction.

EXTRACRANIAL/INTERCRANIAL BYPASS

Senator PROXMIRE. Last week, the Director of the National Institute of Neurological and Communicative Disorders and Stroke told the subcommittee that a controlled clinical trial found that a bypass procedure performed on patients with blocked arteries in the brain—the extracranial/intercranial bypass—should be abandoned in favor of safe or equally effective medical treatments.

Dr. Goldstein told us that the potential savings were, in his words, immense since the operation costs an average of $15,000, and several thousand are performed in the United States each year.

Is this procedure eligible for reimbursement under the Medicare Program? If it is, when will it be stricken from your list of operations eligible for Medicare payments?

Dr. DESMARAIS. It is part of the Medicare benefit package at this point. The study you mention has been viewed as somewhat controversial by some of the surgeons involved. The procedure has been covered by Medicare since 1979 for selected indications in accordance with an assessment completed by the Public Health Service in 1978. As a result of the clinical trials you described, we requested in December 1985 a reassessment by the Public Health Service to determine whether coverage of this procedure should be continued.

Senator PROXMIRE. When do you expect to have that recommendation?

Dr. DESMARAIS. Since this procedure is mentioned in our coverage manual, in order to withdraw coverage, we will have to publish in the Federal Register a notice of our intent to remove it from the benefit package, take note of public comments, and then proceed to publication of a final notice.

Senator PROXMIRE. How long would that procedure take?

Dr. DESMARAIS. The reassessment by the Public Health Service may take up to 6 months, perhaps longer.

Senator PROXMIRE. Would you expect a decision on this issue, one way or the other, within 6 months?

Dr. DESMARAIS. I am not sure. When the Public Health Service reviews an item like this, it announces in the Federal Register that it is doing such a review, and solicits input from medical specialty societies, the American Medical Association, and others. Frequently, it takes quite a bit of time for those organizations to provide input to the Public Health Service. The review, therefore, may take 6 months, or somewhat longer.

Senator PROXMIRE. Would you expect it to take 6 months to 1 year?

Dr. DESMARAIS. Yes.

COVERAGE OF PLASMAPHERESIS

Senator PROXMIRE. Last year, in a statement provided for the hearing record, HCFA said that Medicare does not cover plasmapheresis for the treatment of Guillaine-Barre syndrome although the procedure was estimated by a doctor at a hospital in Milwaukee to have saved millions of dollars in hospital expenses.

You pointed out that the Public Health Service was making an assessment of the safety and effectiveness of the treatment, and that HCFA would decide whether the procedure should be covered under Medicare after receiving a formal recommendation from the Public Health Service. Is that therapy now being covered by Medicare?

Dr. DESMARAIS. I am not sure. I will have to submit that information.

Senator PROXMIRE. Will you let us know, for the record?

Dr. DESMARAIS. Yes.

Senator PROXMIRE. Thank you.

Thank you, Mr. Chairman.

[The information follows:]

COVERAGE OF PLASMAPHERESIS

Medicare has covered plasmapheresis for services performed on or after February 14, 1986.

FISCAL YEAR 1987 BUDGET REQUEST

Senator WEICKER. Dr. Desmarais, as you know, we have consistently objected to including legislative proposals as part of any budget request, yet your budget request is filled with legislative proposals and assumed

budget savings. How much would you need to be added to HCFA's budget request if no legislative savings are assumed?

Dr. DESMARAIS. It would be necessary to add $1.3 billion to the Medicaid request. In program management, the amount to be added would be $4.8 million.

Senator WEICKER. So what is your total, roughly?

Staff calculates, and I don't have the breakdown of it, approximately $4 billion, maybe as much as $5 billion. I think what you should do is to have your staff get together with mine, so we can get that ironed out. It is a rather important part of any budget proceeding.

If you are going to do this, you could really save a lot of time by presenting the two budgets side by side. Up to this point, correct me if I am wrong, but I don't think that in the 3 years that we have gotten all of these legislative proposals that we have had anything take place.

We are not an authorizing committee, we are an appropriations committee.

Mr. GAMBLE. Mr. Chairman, the $2.6 billion is on the appropriated amounts only. The $5.4 billion you cited is correct for all proposals and includes their effect on trust fund outlays.

Senator WEICKER. Let's get that worked out so we have that.

PROPOSED MEDICAID CAP

The budget proposes savings of $1.2 billion by cutting Federal payments below current spending projections for fiscal year 1987. I am now talking about Medicaid. Funds would be distributed to States based on each State's relative share of fiscal year 1985 spending. Future increases would be indexed. However, the Department projects that under current law, the rate of growth in Medicaid expenditures will be 8 percent per year from 1987 to 1991.

How can the States afford to continue quality care to a 3-percent caseload increase with funding that will be reduced by 5 percent?

Dr. DESMARAIS. Of course, along with our proposal, we are recommending a variety of changes to give States additional flexibility. Many States have certainly been very creative in designing reimbursement approaches in their Medicaid programs, particularly through the use of home and community-based waivers and freedom of choice waivers. We are recommending additional flexibility to waive comparability and statewideness requirements so that States can design unique benefit packages for segments of the recipient population. We are also recommending more flexibility in the area of copayments.

Thus, we are proposing a variety of changes to help States deal with limitations in funding.

Senator WEICKER. You further state that legislative proposals for aid for dependent children [AFDC] will produce an additional $284 million savings to Medicaid to assist the States.

Let me get back to my other question, again, given that Congress has not enacted these proposals in the past, aren't these additional savings false assumptions?

Dr. DESMARAIS. We believe the proposals are necessary. If the Congress chooses not to accept these proposals, then certainly the savings will not occur.

Senator WEICKER. Again, I repeat, I think the way around this, because you want to be prepared in carrying forth a budget that your boss proposes, and we have to be prepared in the sense of the congressional side, and I think that it would be helpful if we had the two things set side by side, assumptions realized, and assumptions not realized.

HCFA STAFFING REDUCTION

You propose to reduce the full-time staff of the Health Care Financing Administration by 124 full-time equivalents, or 3 percent from the fiscal year 1986 level, through attrition and streamlining of administrative processes and requirements. When and how do you plan to make those cuts?

Dr. DESMARAIS. Those cuts would occur gradually through attrition. As we lose staff through attrition, which is currently running about 20 per month, we will replace approximately 1 for 3. Priority will be given to the more critical positions as they are vacated. As personnel retire, and so on, some positions are less critical and do not need to be filled. To give you an example, we don't need as many accountants today because we are continuing to move away from cost-based reimbursement.

So we will not have to impose any kind of furlough or reduction in force. The decrease in staffing will be accomplished gradually through attrition.

DISALLOWANCE OF ICF/MR VOCATIONAL AND EDUCATION COSTS

Senator WEICKER. Last year, I objected to the inspector general's policy of disallowing Medicaid funding for vocational and educational activities in intermediate care facilities for the mentally retarded [ICF/MR]. As a result, the inspector general has discontinued auditing these services.

I am, however, now informed that the Health Care Financing Administration intends to pursue disallowances for vocational and educational activities provided in ICF's. Why are you pursuing the disallowance audits, and why are you pursuing a policy that is clearly contradictory both to this committee and the inspector general's policy?

Dr. DESMARAIS. We are aware of your longstanding concern about this particular issue. We are not vigorously pursuing these disallowances at this point, although we certainly are not ignoring them. As you know, in Massachusetts, there has been a district court decision which is adverse to the Department's position on this issue. We intend to appeal that court decision. In the meantime, we are not pursuing or collecting these disallowances.

This issue relates to the underlying policy which governs what is part of the benefit package and what isn't. While it is true that we draw the line on vocational and educational services, we have been working with the States to achieve a clearer policy in this area.

So we must await the decision of the court case in Massachusetts before deciding——

Senator WEICKER. So you are going to take this to the court of appeals.

Dr. DESMARAIS. Yes; the appellate court.

Senator WEICKER. If you lose in the court of appeals, are you going to go to the Supreme Court?

Dr. DESMARAIS. I think that it would be premature to speculate about what we would do. It would depend on the decision. We believe that the judge has gone too far in the Massachusetts case. There is a lot of money at stake here for the Medicaid Program. It is not so much a question of whether the services are important or helpful, but rather whether the particular services should be covered under Medicaid or the Education of Handicapped Children Act of 1975.

As you know, the potential disallowances total over $100 million.

Senator WEICKER. In the meantime, I notice in your justification, you say, "The Department will also pursue disallowances for use of Medicaid funds to provide vocational and educational activities offered at ICF's/MR." You say that you are not vigorously pursuing these disallowances.

Dr. DESMARAIS. Not at this time, but it will depend, again, on the outcome of the court decision.

Senator WEICKER. And on the lobbyists.

Dr. DESMARAIS. There is one thing that we are doing. As a result of the court decision in Massachusetts, a number of States, which had followed the rules, have amended their Medicaid claims for past periods and sent them in for payment. We have chosen not to pay those amended claims, while the appeal of the court decision is in process. We believe that it would be inappropriate to adopt a pay and chase approach for the time being. So that is one area where we are definitely not making payment for those particular services.

Senator WEICKER. What you are saying is that the States have to chase you.

Dr. DESMARAIS. No, sir; I am only saying that some States, which followed the rules, are now going to go back and amend claims for past periods simply because of the court decision. Even though the services have already been rendered and paid for through some other mechanism, some States are now coming in and seeking additional payment from the Medicaid Program. In accordance with the policy that has been in place for many years, we have chosen not to make payment for those amended claims.

However, we are not pursuing at this point the potential disallowances which were uncovered by HCFA or the inspector general.

DELAYS IN MEDICARE CLAIMS PROCESSING

Senator WEICKER. The Gramm-Rudman-Hollings cut in fiscal year 1986 eliminated $13.5 million for claims processing, thereby increasing the work in progress from 9 to 16 days for part A and from 11 to 18

days for part B. The fiscal year 1987 budget does not fully restore the cut even though workloads are projected to increase 6 percent for part A bills and 10.1 percent for part B claims. In addition, work in progress for both part A and part B claims is allowed to slide to 22 working days, an increase of 200 percent.

Why isn't the funding for claims processing fully restored in the fiscal year 1987 budget?

Dr. DESMARAIS. I think this issue relates to something Senator Proxmire referred to earlier, that is, the position that we ought not to pay for claims more promptly than is appropriate under the Prompt Payment Act and under common business practices. In fact, if the Prompt Payment Act did apply to us, we would have been found in violation of it for paying claims too quickly up until now. Given the decisions being made on the budget, we have decided to gradually move to a longer payment cycle.

Senator WEICKER. I have further questions for response to the record.

Do you have further questions, Senator Proxmire?

Senator PROXMIRE. No, Mr. Chairman; but I have some questions for the record also.

HOSPICE SURVEYS

Senator WEICKER. One more here. The budget proposes no hospice surveys for fiscal year 1987, although hospice survey is covered 100 percent in fiscal year 1986 and fiscal year 1985. The hospice benefit was scheduled to expire at the end of fiscal year 1986. In the reconciliation bill passed by the Senate on March 14, the hospice benefit was reauthorized.

In light of the recent action of the reconciliation, do you intend to conduct hospice surveys in 1987?

Dr. DESMARAIS. Yes; if the reconciliation measure becomes law, and the hospice program is continued. A fairly small amount of money is involved in the hospice surveys.

REDUCED NUMBER OF ESRD NETWORK COORDINATING COUNCILS

Senator WEICKER. On the end-stage renal disease networks, your budget proposes to reduce the number of network organizations from the current 32 to 2, and yet the House has sent up here an agreement on the reconciliation legislation which requires as a minimum 14 network organizations. How much more will it cost to fund 14 network organizations, rather than 2?

Dr. DESMARAIS. I don't have that figure.

Senator WEICKER. Will you submit that for the record?

Dr. DESMARAIS. Yes, sir.

[The information follows:]

FUNDING FOR 14 ESRD NETWORK COORDINATING COUNCILS

The cost of funding 14 ESRD network coordinating councils is currently being evaluated.

PLANS FOR NETWORKS

Senator WEICKER. It is unclear from the budget proposal what you are planning to do in the remaining months of fiscal year 1986. What are your plans for the networks in fiscal year 1986, and if your plans include eliminating the networks in fiscal year 1986, how do you propose to accomplish that?

Dr. DESMARAIS. We are proposing a regulatory change which would permit us to reduce the number of councils to a minimum, possibly two, but that number is not set in concrete. Once the regulation is published in final, we would begin to phase out the existing councils. This process is expected to begin in August and be completed by December. In the meantime, we would advertise in the Commerce Business Daily for bidders to submit contract proposals. In this way, we expect to replace the existing organizations with a smaller number.

If this effort proceeds as planned, we may have some additional funds left over that we would not be able to use for the networks. If this indeed happens, we intend to submit a reprogramming request to move what money remains in that account to the Medicare contractor budget.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. I have further questions for response to the record. Thank you very much.

Dr. DESMARAIS. Thank you, Mr. Chairman.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

BUDGET REQUEST

Question. Dr. Desmarais, what was the Health Care Financing Administration's original FY 1987 budget request to the Department? What was the Department's request to OMB?

Answer. The following chart provides HCFA's budget request to the Department and to OMB for FY 1987.

BUDGET SUMMARY
(Dollars in Millions)

	Department Request FY 1987 Estimate	OMB Request FY 1987 estimate
GRANTS TO STATES FOR MEDICAID	$ 23.9	$ 26.1
PAYMENTS TO HEALTH CARE TRUST FUNDS	20.9	20.3
PROGRAM MANAGEMENT		
Research	33.0	22.9
Medicare Contractors	1,017.4	995.5
Contingency Fund	(38.7)	(20.0)
State Certification	60.1	57.0
ESRD	-0-	4.8
Administrative Costs	223.9	222.6
TOTAL, PRGM MNGT	**$ 1334.4**	**$ 1,302.8**

LEGISLATION ON APPROPRIATIONS

Dr. Desmarais, I have consistently objected to including legislative proposals as part of any budget request. The Health Care Financing Administration's budget is filled with legislative proposals and assumed budget savings.

Question. How much would need to be added to HCFA's budget request if no legislative savings are assumed?

Answer. The following table summarizes the requested information.

	Appropriation Request	Assumed Legis.* Savings	Revised Funding Level
Payments	$ 24,708	$ 1,172	$ 25,880
Medicaid	20,357	1,299	20,357
Prg. Mgmt.	1,248	5	1,248
Total	$ 46,313	$ 2,476	$ 47,485

* Additional amount needed

Question. Aren't legislative proposals just a device to make the President's budget -- and the deficit -- appear billions of dollars lower than they really are?

Answer. The legislative proposals we have presented are designed to establish control over programs that, if left in their current state, would erode our country's financial future and that of our citizens through the increasingly higher costs of health care. The Medicare and Medicaid programs administered by HCFA were authorized 20 years ago. That was before we experienced the double digit inflation in the health care industry plus enactment of legislation which added new groups of eligibles, the expansion of benefits and the growth of our elderly population. Left alone the costs of these programs would continue to spiral upward forcing Medicare and Medicaid to command larger and larger shares of Federal revenues and those of the States. What we have proposed is a legislative package that consists of specific proposals to fine-tune Medicare and its reimbursement practices and other proposals which directly impact on Medicaid. All these proposals are intended to hold costs down while continuing to provide high quality health care to our nation's elderly and needy populations.

MEDICAID GROWTH LIMIT

The Budget proposes "savings" of $1.0 billion by cutting Federal payments below current spending projections for FY 1987. Funds would be distributed to States based on each State's relative share of FY 1985 spending. Future increases would be indexed. However, the Department projects that under current law, the rate of growth in Medicaid expenditures will be 8% per year from 1987-1991.

Question. How can the States afford to continue quality care to a 3% caseload increase with funding that will be reduced by 5%?

Answer. In these times of high budget deficits, it is not unusual for States, and Federal agencies for that matter, to be asked to continue to perform many functions with reduced funding. In both Medicare and Medicaid, the Administration's budget contains incentives to improve the efficiency of health care delivery. The Department believes that improved efficiency can be obtained without sacrificing quality care.

The States would not face a budget reduction of 5%, rather their Medicaid expenditures would not grow as fast as originally projected, in the absence of a Cap. While the States would receive $1.0 billion less than the projected total as a result of the Cap, States would not have to reduce expenditures below current levels. In addition, States would be granted increased flexibility in program design and provider reimbursement as a means of achieving the necessary savings.

LEGISLATIVE PROPOSALS TO AFDC

You further state that legislative proposals to AFDC will produce an additional $284 million savings to Medicaid to assist the States.

Question. Given that Congress hasn't enacted these proposals in the past and given that this is the Appropriations committee and not the authorizing committee, aren't these additional "savings" false assumptions?

Answer. While it is true that the Congress has not enacted similar proposals submitted previously by the Administration, the arguments in favor of the FY87 budget are even more compelling in the Gramm-Rudman-Hollings era.

The AFDC proposals are programmatically sound and the Administration is optimistic about their chances for passage. The Medicaid savings due to AFDC proposals are <u>not</u> reflected in the Medicaid request. If Congress enacts the AFDC proposals, this would substantially aid the States in achieving their growth limit targets.

Note: The AFDC budget proposals were originally estimated to save Medicaid $284 million. New estimates peg the Medicaid savings at $169 million.

Mandatory Work and Job Search Requirement	-$70 million
End Parent Benefits when Youngest Child Reaches 16	-$77 million
Require Minor Mothers to Live at Home	-$22 million
Total Medicaid Savings	-$169 million

Question. You state that "a number of measures will be proposed to assist States in meeting the ceilings." What types of measures do you mean?

Answer. States would be given increased flexibility in a number of areas to achieve the budget savings.

States would be given increased flexibility to design their benefit packages for all recipients other than the mandatory categorically needy. States would be able to tailor benefit packages for specific eligibility groups, thereby better targeting their Medicaid dollars.

Federal requirements for "statewideness" and "freedom of choice" would be retained only for mandatory services to mandatory groups; States could assess nominal copayments on mandatory services for mandatory groups, and other restrictions on copayments would be eliminated; and all minimum requirements concerning provider reimbursement rates would be repealed.

States would be able to apply the savings from the second surgical opinion program and the prescription drug reform proposal to the Medicaid cap.

By utilizing all of these proposals, States could reform their Medicaid programs to meet the budget savings requirements.

MEDICAID "CAP" PROPOSAL

Along with your proposal to Cap Medicaid expenditures, a "Hardship Fund" of $300 million would be available in FY 1987 for States with costs above their limit.

Question. If you anticipate the need for this Hardship Fund, why are you proposing a Medicaid Cap?

Answer. The Hardship Fund is a relatively small fund which will be targetted to only a few States who despite their best efforts are unable to restrain their rate of growth. Some States need about a year for their legislatures to enact cost savings measures in their programs. This fund would help them through that transition.

Question. How did you arrive at this $300 million figure?

Answer. The $300 million level was determined to be the appropriate level because it was sufficiently large to provide relief to those States having difficulties adjusting to the new Federal financing limits, while not so large as to provide inappropriate incentives to States in their efforts to control their rates of increase in Medicaid spending.

Question. If you are proposing a Hardship Fund for FY 1987 in anticipation of a transition period, will you be proposing one for FY 1988?

Answer. It is assumed that the overall cap will be enacted for FY 1987 and that the transition period will be from the old program funding in FY 1986 and the new funding arrangement in FY 1987. Therefore, the need for a Hardship Fund will be limited to one year.

MEDICAID FUNDING FOR VOCATIONAL AND EDUCATIONAL ACTIVITIES

Last year, I objected to the Inspector General's Policy of disallowing Medicaid funding for vocational and educational activities in Intermediate Care Facilities for the mentally retarded. As a result, the Inspector General has discontinued auditing these services. Now, however, I am informed that the Health Care Financing Administration (HCFA) intends to pursue disallowances for vocational and educational activities provided in ICFs/MR.

Question. Why are you pursuing these disallowance audits?

Answer. HCFA has not issued any disallowances for ICF/MR educational/vocational training costs in the last year. We would note that on October 7, 1985, the U.S. District Court for the District of Massachusetts ruled against the Department on a Medicaid disallowance for certain ICF/MR educational costs in the State of Massachusetts. We disagree with the Court's decision and have filed an appeal with the U.S. Court of Appeals for the First Circuit to have the decision overturned.

In September of 1985, HCFA issued guidance to the States clarifying its policy and excluding educational services in ICF/MRs. These guidelines were developed with the assistance of a technical advisory group to the State Medicaid Director's Group. Guidelines on reimbursement for vocational services are expected to be issued shortly.

The education guidelines clarified the distinction between services which fall into the realm of both the child's State education plan and the "active treatment" requirement in the Medicaid program (i.e., speech therapy, physical therapy). In 1987, HCFA plans to enforce its policy to exclude Federal Medicaid funding for educational and vocational services in ICF/MRs. The recently issued guidelines should help clarify State versus Federal responsiblity in this area.

Question. Why are you pursuing a policy that is clearly contradictory to the Inspector General's policy?

Answer. As noted in the previous answer we have not issued any disallowances on this issue in the last year. The IG is in the process of finalizing ICF/MR educational vocational training audits that were previously in progress, but no disallowances have been recommended. However, we would note that we are currently in the process of appealing to the

U.S. Court of Appeals for the First Circuit U.S. District Court's decision on the Massachusetts disallowance for educational costs. Additionally, we have issued clarified guidelines on the provision of educational activities in ICF/MRs, and plan to issue vocational guidelines shortly. In 1987, we plan to move forward and enforce our policy on the provision of educational/vocational services in ICF/MRs.

MEDICAID REIMBURSABLE TRAINING SERVICES

Dr. Desmarais, in a letter which I received on February 7 of this year, you stated that "A clarification of the educational services policy was issued in September 1985...", and that you "are still working on a similar clarification for vocational services...".

Question. Can you tell me what services are/are not permissible under these "clarified" regulations?

Answer. The regulations at 42 CFR 441.13(b) include a longstanding prohibition against Medicaid payments to institutions for the mentally retarded for vocational training and educational activities. The purpose of this educational and vocational services exclusion is to avoid Medicaid expenditures for categories of services for which some other State or Federal program is obligated to pay and also to preclude payment for services which are not health-care related.

Public Law 94-142 (The Education of All Handicapped Children Act of 1975) makes Federal education funds available only to States which ensure each handicapped child under age 22 a free and appropriate public education. As specified in the Department of Education's regulations, this law encompasses education and related services, including special education and vocational training suited to each child's needs. In September 1985, HCFA issued revised guidelines to help States distinguish between Medicaid reimbursable ICF/MR services and education services required by Federal and State education laws. The revised guidelines, which were developed in cooperation with State Medicaid representatives, include instructions on how to make these distinctions. As an example, a distinction is made between services which fall within the realm of both a child's State education plan and the "active treatment" requirement in the Medicaid ICF/MR program. If such services (i.e., speech therapy, physical therapy) are provided during periods when the State educational system is not responsible for the individual (i.e., summer, weekends) or as a supplemental activity to reinforce formal State educational training, the service is then eligible for Medicaid reimbursement.

HCFA is currently preparing an instruction for States to use in identifying vocational services provided to ICF/MR clients that are not Medicaid reimbursable. We have discussed the draft instruction with State Medicaid representatives and hope to issue the instruction within the next few months.

ADDITIONAL STAFF FOR ICF/MR SURVEYS

In the FY 1986 appropriations report, this Committee reiterated its 1985 directive that HCFA hire additional surveyors for increased monitoring of Intermediate Care Facilities for the Mentally Retarded. Finally, I see that HCFA is planning to comply with this directive.

Question. Can you tell me when the last of the remaining 12 surveyors will come on board?

Answer. We anticipate that all surveyors will be hired by the end of this fiscal year.

Question. What accounts for the delay in hiring these surveyors?

Answer. In January 1986, recruitment actions were initiated to hire 12 additional surveyors. Completion of the hiring process was delayed, however, as a result of a Department-wide hiring restriction that was in effect from February 14 to March 31. Recruitment action has now resumed and our goal is to hire the surveyors as soon as possible.

STATE CERTIFICATION - SKILLED NURSING FACILITIES (SNFS)

The budget justification emphasizes that annual surveys will be conducted for Skilled Nursing Facilities (SNFs) to ensure that providers comply with program standards. However, a new study by the National Academy of Sciences calls for much stronger Federal Regulation of nursing homes. In addition, the study emphasized that the new regulations should focus more on quality of care and less on review of paper work.

Question. Of the skilled nursing facilities annually surveyed, how many are found deficient?

Answer. In order to participate in the Medicare and Medicaid programs, SNFs must be in compliance with Conditions of Participation (broad clusters of health and safety requirements). The conditions are comprised of 87 constituent standards and, accordingly, it is unlikely that a SNF will be found to meet all 87 standards when surveyed. In fact, a SNF may fail to comply with one or more of these standards and continue to participate in the program as long as it submits an acceptable plan of correction. If, however, a group of deficient standards, when taken together, indicates that there is a serious breakdown in the facility's ability to provide adequate health care services to its patients, then the facility is considered to be out of compliance with the related Condition of Participation and the facility cannot be certified until the needed corrections are made.

Our data indicate that, of the 6,749 SNFs certified to participate in the Medicare and Medicare/Medicaid programs, approximately 61 percent or 4,128 of these facilities surveyed in FY85 had standard (major sub-component of a condition) level deficiencies.

Question. How many of these "deficient" providers are repeat offenders?

Answer. We do not have aggregate data on repeat offenders that is readily available. However, HCFA regional offices monitor both the nature and extent of facility compliance with program requirements. New termination procedures require that action to terminate a facility's participation be taken when deficiencies, either alone or in combination with others, adversely affect patient health and safety or limit a facility's capacity to furnish an adequate level or quality of care. In addition, a facility's compliance history is considered before a decision to reapprove is made.

STATE CERTIFICATION - SKILLED NURSING FACILITIES (SNFs)

Question. What penalties are imposed on repeat offenders?

Answer. If a SNF continues to be out of compliance with the same standard(s) at the end of the term of the agreement, a new agreement may not be filed and participation in the Medicare program is ended. Participation may continue if compliance was achieved, but, for reasons beyond the control of the provider, the deficiency reoccurred. For example, a nurse quits just prior to survey causing the nursing standard, which was not met at the time of the last recertification survey, again to be not met. Also, HCFA plans to propose regulations that would enable termination based on a provider's unwillingness or inability to maintain compliance with program requirements.

The Secretary is also developing intermediate sanctions to deny a facility that is in noncompliance (minor deficiencies) reimbursement for any new admissions.

Question. How many "deficient" SNFs are terminated?

Answer. There were 82 terminations processed nationwide for Medicare and Medicare-Medicaid SNFs during FY 85 (60-voluntary, 22-involuntary). (The voluntary terminations include those facilities that merge with another, close or withdraw from the program due to dissatisfaction with reimbursement or because of the risk of involuntary termination; involuntary terminations include those facilities that fail to meet the health and safety requirements and/or fail to comply with provisions of the provider agreement).

STATE CERTIFICATION - SKILLED NURSING FACILITIES

One of the President's Medicaid proposals is to reduce Federal matching rates from 75 percent to 50 percent for survey and certification activities.

Question. If this proposal is enacted, won't States have less funds available to inspect these facilities and enforce regulations?

Answer. States will have less Federal matching funds available for inspecting facilities, however, the total amount of Federal/State resources directed to surveys will remain the same. Both Federal and State governments have a dual responsibility for administering the Medicaid program, therefore, the Administration proposes that States be required to share equally in the cost of inspections. This proposal will have no adverse impact on States' ability to enforce regulations and they will continue a program of annual inspections for all Medicaid facilities.

STATE CERTIFICATION

Your budget justification states that "Funds budgeted in FY 1987 will ensure that facilities having deficiencies on previous surveys will receive appropriate follow-up."

Question. Do you have any plans for developing more rigorous survey and follow-up methods to determine whether corrections have been made?

Answer. A new Long-Term Care survey process which focuses on patient care issues has been developed and is ready for implementation. The new LTC survey should provide more meaningful information allowing us to monitor the facility's effectiveness with respect to the quality of care provided and the impact on the quality of the patient's life. The current procedures provide for timely appropriate follow-up of survey findings. The revised termination procedures provide a more timely process eliminating facilities in non-compliance.

STATE CERTIFICATION

Question. What is the deficiency rate for each type of facility that is surveyed?

Answer. The deficiency rate for each type of facility surveyed in FY85 is as follows:

Medicare	Maximum No. of Regulations per Facility	FY 85 Average No. of Deficiencies per Facility
Hospitals (Non-Accredited)	364	14.52
SNFs (18 and 18/19)	431	14.76
Home Health Agencies	37	2.01
Independent Laboratories	107	3.27
End-Stage Renal Disease	103	3.28
Hospices	185	4.11
Other	81	2.12
Medicaid		
SNFs (19 only)	431	13.36
ICFs	242	6.22
ICFs (Mentally Retarded)	671	21.18

Question. Of the amount of total participating facilities found deficient in each facility type, how many, or what percentage, are terminated?

Answer. HCFA is committed to terminating all facilities that fail to meet conditions of participation. The total number of terminations (voluntary and involuntary) based on the facility being unable or unwilling to correct cited deficiencies is as follows:

Medicare	Voluntary	Involuntary	Total
Hospitals (all)	64	4	68
SNFs (18 and 18/19)	60	22	82
Home Health Agencies	312	3	315
Independent Laboratories	280	10	290
End-Stage Renal Disease	12	0	12
Hospices	2	0	2
Other	144	4	148
Medicaid			
SNFs (19 only)	43	6	49
ICFs	88	20	108
ICFs (Mentally Retarded)	26	11	37

1/ Voluntary terminations include those facilities that merge with another, close or withdraw from the program due to dissatisfaction with reimbursement rate or because of the risk of involuntary termination.

2/ Involuntary terminations include those facilities that fail to meet the health and safety requirements and fail to comply with provisions of the provider agreement.

CLAIMS PROCESSING

The Gramm-Rudman-Hollings cut in FY 1986 eliminated $13.5 million for claims processing, thereby increasing the work in progress from 9 to 16 days for Part A and from 11 to 18 days for Part B. The FY 1987 budget does not fully restore the cut, even though workloads are projected to increase 6% for Part A bills and 10.1% for Part B claims. In addition, work in progress for both Part A and Part B claims is allowed to slide to 22 working days, an increase of 200%.

Question. Why isn't the funding for claims processing fully restored in the FY 1987 budget?

Answer. We are funding claims processing fully in FY 1987 to maintain work in progress at 22 days. It should be noted that, as indicated above, we believe that the Medicare program should not pay its bills faster than what is common business practice. Although the Medicare program is not subject to the Prompt Payment Act, we are using its thirty day turnaround as a guide for establishing a timeframe for payment of a clean bill submitted to a Medicare contractor.

PROCESSING MEDICARE CLAIMS

Question. How do you justify a 200 percent increase in the time it takes to process a Medicare claim?

Answer. At the end of FY 1985, the average days work on hand at a Part A intermediary was 9 days and at a Part B carrier, it was 11 days. Gradually, we project the days work on hand will increase to 22 days for both intermediaries and carriers by the end of FY 1987. This increase was necessitated by the across-the-board reductions mandated in FY 1986 by the Gramm-Rudman-Hollings law. In FY 1987, we intend to process Medicare claims using the Prompt Payment Act as a guide to balance beneficiary and provider cash flow concerns as well as increase interest income for the trust funds.

Question. It is my understanding that 30% of Part B claims are paid directly to the beneficiary. Since many of these beneficiaries are on fixed incomes, won't they be subjected to cash flow problems?

Answer. We do not believe that beneficiaries will be seriously affected by an increase in contractor work in progress. Because we intend to use the Prompt Payment Act as a guide for payment, beneficiary bills will be processed within approximately 30 days from receipt of a bill. We do not feel that this timeframe will cause undue hardship for our beneficiaries. Of course, with the availability of participating physicians and suppliers, beneficiaries can avoid altogether any initial cash outlay.

Question. Don't you think these processing delays will seriously harm the public's confidence and credibility in the Medicare system?

Answer. Because the increase in days work-in-process will occur gradually over two years, we believe the public confidence in the Medicare program will remain strong. Early objections should dissipate as beneficiaries and providers become accustomed to the new payment timeframes.

INTEREST TO TRUST FUNDS

It has been said that increasing the work-in-process amount of days will generate an additional amount of interest to the trust funds.

Question. How much interest do you project will be generated?

Answer. The following chart shows the substantial earnings to the trust funds by increasing days work in process:

Savings to Trust Fund:	FY86	FY 87
PART A OUTLAY	$ 360.0M	$ 425.0M
INTEREST	$ 20.0M	$ 50.0M
SUBTOTAL	$ 380.0M	$ 475.0M
PART B OUTLAY	$ 625.0M	$ 625.0M
INTEREST	$ 50.0M	$ 100.0M
SUBTOTAL	$ 675.0M	$ 725.0M
TOTAL	$1,055.0M	$ 1,200.0M

Question. Is this additional interest income required at the expense of delayed payments to beneficiaries and providers?

Answer. In our view the increased interest income results from the use of common business practice techniques. We do not expect undue hardships on beneficiaries or providers. Over 53% of Part A dollars are reimbursed via the Periodic Interim Payment methodology negating any payment timeframe changes for these providers. In addition, beneficiaries using participating physicians and suppliers or HMO/CMPs will not be affected by these changes.

CONTINGENCY FUND

The budget proposes a contingency fund of $50 million, an increase of $35.6 million over FY 1986.

Question. For what purposes do you anticipate the contingency fund will be used in FY 1987?

Answer. As in the past, we will use the contingency fund to fund workloads or operating costs not anticipated at the time the budget was formulated. These could include increases in claims, reconsiderations, inquiries, etc. In addition, the contingency money could be used for unanticipated inflation as well as legislative and other changes.

Question. Why the large increase over FY 1986?

Answer. We believe that it is appropriate during this time of fiscal restraint to adhere to tough budget estimating principles while increasing the elasticity to absorb new activities or new workloads. Thus we have increased our normal $15 to $20 million contingency request to $50 million.

Question. Do you anticipate deficiencies in the amount of money allocated for claims processing?

Answer. We do not project deficiencies in the money allocated for claims processing if our volume estimates are accurate. We are evaluating our volume estimates as the year progresses and will allocate additional resources if they are required.

The purpose of the contingency fund is "to process workloads not anticipated in the budget estimates" (bill language). However, HCFA must go through the Department and OMB to allocate and release the funds. For example, $13.8 million of the $14.4 million FY 1986 contingency fund has been requested for release, but has not been finally approved by OMB. Yet, we understand that Medicare contractors will have to slow down the processing of claims in order to operate within the funding constraint of $920 million.

Question. Should there be a different mechanism for funding unanticipated workloads other than the contingency fund?

Answer. HCFA has not at the present time requested use of the contingency fund from OMB. We believe the contingency is the best mechanism to assure adequate funding of unanticipated workloads. Without a contingency, we would need to request a supplemental appropriation, greatly lengthening the process.

Question. Why involve OMB?

Answer. Under the Antideficiency Act, agencies submit apportionment requests to OMB. The statute requires that OMB apportions funds to assure efficient and economical use of

funds, as well as preventing obligation or expenditure of funds at a rate which could result in a deficiency.

STATE CERTIFICATION WORKLOAD FUNDING REQUIREMENTS - HOSPICES

The budget proposes no Hospice surveys for FY 1987, although Hospice survey coverage was 100 percent in FY 1986 and FY 1985. The Hospice benefit was scheduled to expire at the end of FY 1986. However, in the Reconciliation Bill passed by the Senate on March 14, the Hospice benefit was reauthorized.

Question. In light of the recent action on the Reconciliation bill, do you plan to conduct hospice surveys in 1987?

Answer. Yes. In order for hospices to receive reimbursement for providing care to Medicaid and Medicare beneficiaries, they must be surveyed and certified.

Question. What do you anticipate as an appropriate level of survey coverage?

Answer. We continue to support a 100 percent survey coverage level for hospices. New facility types traditionally experience more problems than established ones, and require additional oversight. As hospices become accustomed to meeting standards and conditions for participation, we will reexamine the current recommended coverage level.

Question. What do you estimate the cost of that to be?

Answer. By the end of FY 1987, the number of hospices participating in the program is estimated to be 310. The estimated cost to conduct 310 initial and/or recertification surveys together with approximately 124 followup visits is $820,000. Funds will be reallocated, within the current funding request, to ensure that survey coverage for hospices is continued at the appropriate level.

ALZHEIMER'S DISEASE STUDIES

Last year, the Secretary announced that the Health Care Financing Administration would be putting a special emphasis on projects designed to evaluate in-home care for victims of Alzheimer's disease.

Question. Would you provide us with a status report on that effort?

Answer. HCFA's Office of Research and Demonstrations

(ORD) has included as a priority area in its current cooperative agreements and grant solicitation projects which evaluate the effects of innovative State and local programs to promote home care by families or by other community support arrangements. Two applications for projects to study home care arrangements were received and they are now being reviewed. Currently, HCFA has two research and demonstration activities designed to test the effectiveness of providing assistance to families with individuals at risk of institutional care, including those with Alzheimer's disease. The University of Washington project, entitled "Alternate Family Support Strategies," provides three types of support to families:

1. Paid respite care, up to a maximum dollar limit per family, provided by a home health agency, and adult day care center or a skilled nursing facility.

2. Training of family caregivers and case management.

3. Training and case management in conjunction with paid respite care.

Of the 541 Medicare beneficiaries and their families currently receiving services at the Seattle site of this project, 108 participants are diagnosed as having Alzheimer's disease.

The goal of the "Respite Care Co-op for Impaired Elderly" project is to develop a model cooperative which provides respite for family caregivers of impaired elderly. HCFA is funding the South Central Commission on Aging in Kalamazoo, Michigan for 3 years to establish several co-ops with a maximum of 10 participant families in each. The model utilizes a cooperative committee composed of impaired elderly, their family caregivers, and representatives from community agencies. The committee, with a program coordinator, works to establish policies and procedures and to recruit families to participate. In a fashion similar to babysitting co-ops, family members pay for care received with care given. No findings are available at this time.

ALZHEIMER'S DISEASE STUDIES

Question. What do the preliminary results show, in terms of managing the Alzheimer's patient at home?

Answer. The final evaluation of the demonstration is projected for completion by March 1987. Early reports have shown trends in the family preference in the use of home health respite care rather than skilled nursing facility respite service. These reports also show promise in the ability of family support systems to delay or avoid the institutionalization of the frail family member.

In last year's report, we asked that you conduct a study on the cost implications of extending Medicare coverage to victims of Alzheimber's disease.

Question. Has work on the study already begun?

Answer. HCFA does not currently have any projects dealing with "the cost implications of extending Medicare coverage to victims of Alzheimer's disease." We included in our January 30, 1985 Federal Register notice of research and demonstration grant/cooperative agreement funding priorities the study of Alzheimer's disease; however, no acceptable related proposal was received for either the FY 1985 (April 15) cycle or the FY 1986 (November 4) cycle. Generally, we have not conducted studies that consider the issue of extending Medicare coverage to disease-specific categories of individuals.

ALZHEIMERS VICTIMS

Question. For the time being, what alternatives are available to families when it comes to care and treatment for Alzheimer's victims?

Answer. HCFA's Office of Research and Demonstrations is performing several studies concerning patients who are beneficiaries under the Medicare program and enrollees in State Medicaid programs who receive care in long-term care institutions. It is important to note that the elderly with medical problems tend to have more than one problem at any one point in time. It may not be appropriate to single out one particular condition. Patients with dementia which stems from neurologic and psychiatric etiologies also tend to have accompanying physical illness problems such as heart disease, incontinence, arthritis, and other concomitant conditions. It is for this reason that we study the Medicare and Medicaid populations as groups rather than segmenting studies by patient diagnosis.

Our demonstration efforts have been aimed at improving quality and access to care by developing reimbursement systems which pay according to the amount of service needed by the patients. We currently are funding studies in New York and Texas which use the Resource Utilization Group (RUGs) nursing home case-mix system developed by Yale University. These studies are attempting to develop reimbursement systems in which a nursing home's reimbursement rate is based on its case-mix.

As a group, patients with a primary diagnosis of dementia tend to require more assistance with activities of daily living and tend to have a higher frequency of severe behavioral problems than nondementia patients. Since case-mix reimbursement systems provide higher payment rates for higher levels of disability and occurrence of severe behavioral problems, these systems can provide strong incentives for facilities to accept these patients. In addition, for patients with Alzheimer's and related dementia disorders, the progress of the disease is such that more intensive intervention is anticipated over a fairly brief period of time. A facility's rates can be revised periodically to reflect the changes in case mix. Thus,

patients who have increased levels of disability will receive increased levels of payment consistent with their needs.

If successful, case-mix payment systems will provide radical improvements in the ability to identify patient needs, and to direct resources to patients based on those needs. Patients requiring additional care, whether because of dementia or physical impairment, will be able to receive support consistent with those relative needs. This case-mix approach represents a significant improvement in our ability to direct resources to those most in need.

FEDERAL ADMINISTRATIVE COSTS - STAFFING LEVELS

You propose to reduce the full-time staff of the Health Care Financing Administration by 124 full-time equivalents (FTEs), or 3 percent from the FY 1986 level, through attrition and streamlining of administrative processes and requirements.

Question. When and how do you plan to make those cuts?

Answer. Staffing cuts will be made through attrition thereby resulting in no adverse impact to HCFA staff.

Question. If you rely on staff attrition to make the proposed cuts, how will you ensure that the reductions are not disproportionately distributed? For example, in the area of survey and certification, how will you go about staff reductions?

Answer. For the past several years, personnel levels within the Agency have been established to effect staffing reductions by streamlining administrative staff as well as reducing those functions that were considered less essential to the mission of the Agency. While it was decided that the Agency's total employment level would be allowed to decrease by following a principle of attrition, priorities were established and efforts were made to reallocate employees from low-priority to high-priority functions. In this way the devastating morale effects of a Reduction-in-Force (RIF) were avoided and, at the same time, HCFA was streamlined to accomplish its mission within the constraints of a lower staffing level.

These staffing levels are continually monitored and adjusted to accommodate shifts in priorities. When vacancies occur in low-priority functions, the positions are reallocated to higher priority functions. Thus, it is possible to achieve staff reductions through attrition while maintaining or increasing staffing levels in critical areas such as survey and certification.

END STAGE RENAL DISEASE NETWORKS

Your budget proposes to reduce the number of network organizations from the current 32 to 2. Yet the House and Senate appear near agreement on reconciliation legislation which requires a minimum of 14 network organizations.

Question. How much more will it cost to fund 14 networks rather than the 2 you had planned?

Answer. The cost of funding 14 ESRD Network Coordinating Councils is currently being evaluated.

Question. What are your plans for the Networks in FY 1986?

Answer. We will continue to fund the existing ESRD Networks at their authorized level through FY 1986.

Question. If your plans include eliminating networks in FY 1986, how do you propose to accomplish this?

Answer. We do not propose to eliminate ESRD Networks in FY 1986. We have, however, proposed regulations that would permit an administrative redesignation of the areas that comprise the Networks and to establish new Network organizations to fulfill the statutorily mandated functions. This regulation will be effective beginning in FY 1987.

MEDICAID - SECOND SURGICAL OPINION PROGRAMS

The budget proposes to require States to operate mandatory second surgical opinion programs and inpatient hospital preadmission review programs, for an estimated savings of $80 million in FY 1987.

Question. In the event that the second opinion is different from the first, would the beneficiary still be able to receive the operation if he or she desires?

Answer. Yes. The regulation on Mandatory Second Surgical Opinion Program under Medicaid does not interfere with the patient's freedom of choice on whether or not to undergo the surgery nor does it limit payment to those situations where the second opinion confirms the first. The regulation requires only that a second opinion be obtained for certain elective surgical procedures.

Question. How would this proposal affect any State program already in existence?

Answer. States with existing review programs that prevent unnecessary surgery and are cost-effective would be allowed to obtain HCFA approval of their programs in lieu of meeting the

new requirements. If HCFA determines that the existing system fails to meet the SSOP objectives, States will be given the option of upgrading existing programs to meet the objective of the regulation, rather than implementing a mandatory second opinion program.

PREADMISSION REVIEW

Question. Describe your proposed hospital preadmission certification program. Which procedures do you intend to include? What would happen to State programs already in existence?

Answer. We are still developing our Medicaid preadmission review program. We intend to incorporate the new requirements, when developed, into the utilization control regulations. These regulations specify the medical review activities a State must carry out in order to receive Federal financial participation for the services it provides in the institutional setting. (It is worth noting here that many of the States with existing preadmission review programs have instituted them within the rubric of the utilization control program.)

We are still studying various options for review. Currently, our tentative view is that we would require that a State have a program in place that enables it to identify and review cases in which the potential for an inappropriate admission is high. In fashioning our requirements we would, of course, attempt to assure that existing State programs that are effective will remain unaffected.

MEDICAID LIMIT ADMINISTRATIVE COSTS

The Administration proposes to eliminate special matching rates for information systems, family planning administration, medical personnel used for survey and certification activities, contracts with peer review organizations, and fraud control. These activities would be matched at 50 percent.

Question. What would be the impact of your proposal on the efficient administration of State Medicaid programs?

Answer. The original purpose of establishing the enhanced matching rates, ranging from 90 percent to 75 percent, was to encourage the State agencies to employ or develop those aspects, such as those you have depicted, to enhance their programs. It was an enticement offered to get the States to use the services so that they could see the benefits to be realized. Once having seen the efficacy of these programs or systems, the enhanced matching served its purpose. Reduction of the matching rate is unlikely to produce the adverse reaction of abandonment of efficient systems in favor of inefficient systems as the States' own resources are at stake

also. Thus, we cannot foresee that there will be any adverse reaction.

Question. How will States be able to absorb the impact of this proposal in light of your proposals to place a cap on Medicaid benefit payments?

Answer. States will be able to continue their current service levels to those groups currently in their plan, however some small adjustments may be necessary for non-mandatory services or extensions of coverage to optional groups. In these adjustments it is likely that sufficient leeway may be had to make up such losses in Federal matching as may be experienced in the elimination of enhanced of matching for administration.

The Administration also proposes to reduce the matching rate for States with per recipient administrative expenditures over 175 percent of the national median? The matching rate would be reduced from 50 percent to 25 percent for those costs which exceed the 175 percent limit.

Question. How many States have per recipient administrative expenditures over 275 percent of the national median? Identify them.

Answer. At the present time our data are incomplete for actual State expenditures and recipient counts for 1985; however, estimates for 1984 show that the following 7 States would have been affected in 1984: Nevada, New Hampshire, New York, North Dakota, Oregon, Utah and Vermont.

MEDICAID - PRESCRIPTION DRUG REIMBURSEMENT

The budget proposes to modify prescription drug reimbursement under Medicaid, including initiatives to increase generic drug substitutions, for an estimated savings of $38 million in FY 1987.

Question. How would your proposal modify prescription drug reimbursment under Medicaid? In particular, what initiatives do you intend to take to increase generic drug substitution?

Answer. We plan to publish a Notice of Proposed Rulemaking (NPRM) in June that will propose three alternatives to current Medicaid reimbursement policy: (1) the Pharmacists' Incentive Program, (2) the Competitive Incentive Program, and (3) a revised Maximum Allowable Cost Program. The Pharmacist Incentive Program (PhIP), in particular, should offer great promise for increasing generic drug substitution because of the potential for savings by providing an economic incentive for

the pharmacist to purchase and dispense less costly FDA determined therapeutically equivalent drug products in lieu of brand name drugs. PhIP can be easily implemented and offers savings in excess of $60 million based on actual paid claim data from the States. Additional savings are likely when new generic drugs are added to the PhIP savings estimate.

FREEZE CLINICAL LABORATORY FEES

The budget proposes to freeze the fee schedule amounts for clinical laboratory services for one year, for an estimated savings of $55 million in FY 1987. In addition, reasonable cost limits for clinical laboratory fees will be established by regulation when the fee schedule for tests performed in hospital outpatient departments expires July 1987.

Question. Is there now a significant variation in fees among the nation's clinical laboratories? If so, is it possible that your proposal could lock in inequitable schedules?

Answer. There is a substantial variation in the fee schedules across the country. However, section 9303 of COBRA will narrow these differences since a limit at 115 percent of the national median fee is being established effective July 1, 1986. In addition, a national fee schedule is scheduled for implementation January 1, 1988. The proposal to impose a 1-year freeze on updating the fee schedules does not add to or reduce the variations in payment.

Question. Emergency tests can sometimes be more expensive than routine ones. Transporting samples from the patient to the laboratory, particularly in rural areas, can also pose additional costs. How do you plan to deal with these issues in the future?

Answer. Special costs in emergency circumstances are unrelated to the methodology of payment or the imposition of a freeze. Such circumstances existed before fee schedules and will continue regardless of modifications or changes in reimbursement approach. Carriers have established policies in the past to deal with these circumstances and such policies are still applicable. In the process of rulemaking, we will be reiterating the instruction to our carriers to judge the reasonableness of charges in emergency situations on a case-by-case basis.

MEDICAID - REFUGEE TRANSFER

The budget proposes to move those refugees needing medical assistance from the Medicaid rolls and require instead that they be assisted primarily by the special refugee medical assistance program funded under the Immigration and Nationality Act.

Question. Describe the special characteristics and medical needs of the Medicaid beneficiaries which would be affected by this proposal?

Answer. The budget proposes to transfer refugees from the program of aid to families with dependent children to the refugee cash assistance (RCA) program. For reasons of administrative consistency and simplicity refugees who receive RCA would then receive medical assistance under the program of refugee medical assistance (RMA) rather than through the Medicaid program. We believe that the RMA program is the most logical mechanism for refugees to receive needed medical assistance during the first 18 months.

Medicaid matching grants to the States are exempt from sequestrations under the Balanced Budget and Emergency Deficit Control Act of 1985; however, the special refugee medical assistance program funded under the Immigration and Nationality Act is not exempt from Gramm-Rudman cuts.

Question. What effect would this have on the benefits to these Medicaid-Eligible refugees?

Answer. The transfer of refugees from the Medicaid program to the program of refugee medical assistance (RMA) is not expected to affect the benefits available to refugees. Benefits under RMA would be available to refugees for 18 months, after which time a refugee could receive Medicaid if eligible under that program.

MODIFY ESRD RATES

The Administration budget proposes to revise the weighting of the End-Stage Renal Disease (ESRD) treatment and facility mix in rate computations. This weighting would reduce the facility rates. Physician rates would be reduced to take into account a recent General Accounting Office study. The estimated savings for FY 1987 are $90 million.

Question. What studies or data support the reduction of the payment rates for physician and facility dialysis services?

Answer. Facility.--Audits of end stage renal disease (ESRD) facility costs for furnishing outpatient maintenance dialysis were performed in the fall of 1983. The results of these audits confirmed the trend established by earlier audits: that the costs of the overall dialysis service have not followed general inflation. Furthermore, taking into account estimated adjustments for disallowances normally associated with auditing, unaudited cost data for 1984 reported by the same independent facilities that were in the 1983 national addition the number of dialysis facilities continues to increase. Since May 11, 1983, the date we published final regulations for the ESRD composite rate, there have been 177

new facilities. Currently, there are 1,380 certified renal facilities that furnish outpatient maintenance dialysis. We can infer from this continued growth that the ESRD program composite rates have not discouraged the entry of new providers of dialysis services.

Physician.--As you indicated the reduction in physician reimbursement stems from a General Accounting Office (GAO) report issued in February 1985 (report No. GAO/HRD-85-14). This report indicated that physicians furnish fewer services to home dialysis patients than was previously believed. When the physician payment rates were set, the formula included a factor for home dialysis patients of 70%. This meant that physicians furnished 70% as many services to home patients than to facility patients. The GAO report showed this factor should have been 26%. Substituting this factor into the formula which averages the services provided to home and facility patients by the number of each type of patient results in the reduction (of 7.88%).

Question. ESRD prospective payment rates were intended to encourage home dialysis. How would this proposal affect those incentives?

Answer. The composite rate system promotes home dialysis by paying the same payment rate for lower cost home dialysis as for in-facility dialysis. In this way there is a greater profit available for home dialysis as compared to in-facility dialysis. This feature of the composite rate will remain the same. There may be an additional incentive for using home dialysis under the proposed rates because these rates are lower and the profit for in-facility dialysis will be reduced.

Physician reimbursement functions in the same way as the composite rate system for facilites.

SIMPLIFY PROCESSING OF PART A BILLS

The budget proposes to assign the responsibility for collecting deductible and coinsurance amounts from beneficiaries who stay in two or more hospitals during a single spell of illness in the order in which hospitals submit claims for Medicare payments.

Question. Will this proposal create addditional administrative costs for Medicare intermediaries? If so, is this accounted for elsewhere in the budget?

Answer. This proposal will not create additional administrative costs for Medicare intermediaries. In fact, the proposal will reduce administrative costs because it will greatly simplify the billing process. This will represent a

significant savings in administrative costs of $4.0 million in FY 87 and $16.0 million in FY 88-91.

MEDICARE PAYMENT OF DIRECT MEDICAL EDUCATION PAYMENT

The budget proposes to eliminate payments for education subsidies while retaining reasonable payments for services of residents and interns only. Currently, Medicare pays hospitals on a reasonable cost basis for direct costs, such as resident and teaching salaries and education expenses of residents, allied health professionals and nurses. The proposed savings for FY 1987 are $495 million.

Question. How do you propose to establish hospital-specific limits on payments for intern and resident salaries.

Answer. COBRA has superseeded the President's Budget in this area and lays out a method to set those limits. We will issue regulations implementing the law.

PROSPECTIVE PAYMENT POLICY

The budget proposes to include capital costs in the prospective payment system rates. Hospital capital costs are excluded from the prospective payment system until October 1, 1986, and are currently being reimbursed on a cost basis. The estimated savings for FY 1987 are $450 million.

Question. Describe the transition process for bringing capital costs under prospective payments. Do you believe that the transition is long enough?

Answer. The Administration is proposing to set a national per-case payment for capital, to be incorporated into the PPS standardized amounts as an adjustment to the nonlabor portion for urban and rural areas, phased in over four years, effective with cost reporting periods beginning on or after October 1, 1986. During the phase-in period, payments would be based on a combination of a national rate and a hospital-specific rate. The national capital-related rate would be based on fully-audited FY 1983 cost data and the hospital-specific capital-related rate would be calculated based on fully audited FY 1986 data.

During the transition period, the hospital-specific payment would be based on the actual allowable capital costs for each year of the transition, limited by a reasonable growth factor tied to the actual increase in the capital component of the hospital market basket applied to each hospital's capital cost base (FY 1986).

The proposed schedule for the phase-in period to full national payment rates would be as follows:

	National	Hospital-Specific
FY 1987	20%	80% (includes 75% interest on funded depreciation)
FY 1988	40%	60% (includes 50% interest on funded depreciation)
FY 1989	60%	40% (includes 25% interest on funded depreciation)
FY 1990	80%	20%
FY 1991	100%	0%

It is our intent to provide highly leveraged hospitals with adequate time to realign their obligations with their projected revenues. In establishing this policy, we believe it to be the responsibility of the hospital industry to bring its capacity into line with demand, and not the responsibility of the Federal government to continue to fund a growing amount of idle capacity.

Question. What would happen to hospitals with construction projects in progress that will not be completed until after the transition has been completed?

Answer. The ultimate goal of incorporating capital into PPS is to eliminate the distinction between capital and other inpatient operating costs. Under a single payment system, hospitals would be able to plan and budget for the total cost of Medicare patients relative to total Medicare revenue, thus enabling them to choose the optimal mix of capital and other inputs in providing health care services.

Question. Will the capital payments be adjusted to take into account geographical variations in construction costs?

Answer. The Administration's proposal would be consistent with the current PPS policy for inpatient operating expenses. That is, separate standardized capital payment amounts will be established for rural and urban hospitals, as designated by current PPS regulations.

Question. Will the capital payments be annually adjusted to reflect increased construction and borrowing costs?

Answer. Section 1886(e)(4) of the Social Security Act provides that the Secretary will annually, beginning with Federal Fiscal Year 1986, determine the percentage change in the PPS rates. In making this determination, the Secretary must take into account the recommendations of the Prospective Payment Assessment Commission, as well as amounts necessary for

the efficient and effective delivery of medically appropriate and necessary care of high quality. Also, in making this determination, the Secretary will review any changes in the hospital market basket, which is a measure of the change in the costs of goods and services which hospitals purchase in order to provide services to patients. Therefore, as capital is incorporated into the PPS rates, the market basket will be revised to incorporate a capital component, and the increase in the market basket will reflect changes in the cost of capital in addition to other goods and services purchased by hospitals.

Question. If capital costs were to increase, what would this proposal do to a hospital's ability to meet its capital needs?

Answer. The Administration believes that the capital payment policy adopted should be neutral with respect to capital versus operating cost trade-offs. Currently, a hospital that can substitute capital for operating costs (and assume the risk of additional capital acquisitions) receives more in total Medicare payments (i.e., fixed DRG payments plus increased cost reimbursement for capital expenditures) than a similar hospital that does not make such a substitution. Therefore, the payment method should not favor either capital or operating costs. An all-inclusive payment rate (no distinction between capital and operating payments) would allow individual providers the flexibility to make what they consider to be the most cost-effective decision based on the unique characteristics of their institutions.

APPLY COST-SHARING TO AMBULATORY SURGERY

The budget proposes to impose the standard Part B coinsurance and deductible for surgery done in ambulatory surgical centers.

Question. Will this proposal create incentives for beneficiaries to use inpatient rather than outpatient surgical services?

Answer. The inpatient hospital deductible is currently $492. Generally, this would be far in excess of the 20 percent Part B coinsurance for most ASC approved procedures. In addition, PROs are carefully monitoring improper use of inpatient services when a procedure can be safely performed in an outpatient center.

Question. What do you expect the financial impact of this cost-sharing proposal will be to a given beneficiary?

Answer. Our actuaries estimate that the impact per beneficiary using these services would be $95.

MODIFY NON-PHYSICIAN PAYMENTS

The budget proposes to review reasonable charge levels and revise payments where appropriate to reduce excessive charges for non-physician services (primarily durable medical equipment). The proposed savings for FY 1987 are $70 million.

Question. Please describe how you propose to review reasonable charge levels and revise payments. In how many instances do you believe the payment amount would be revised because they are excessive?

Answer. We plan to help control outlays for nonphysician payments by expanded application of lowest charge level (LCL) limits and through carrier and HCFA use of inherent reasonableness authority. We do not know at this time how many instances will be found where these limits are appropriate. Generally, items will be identified for potential inclusion by their being commonly available and not differing widely in quality. The use of inherent reasonableness authority would be considered based on information brought to carrier and HCFA attention suggesting that prices are grossly out of line.

Question. We understand that beneficiaries have had a number of concerns with the recently issued rent/purchase durable medical equipment (DME) policy. Are you contemplating any change to this policy?

Answer. We are unaware of any adverse effects on the ability of our beneficiaries to obtain needed DME and have not received any complaints. We have no plans for any major policy changes.

INCREASE AND MODIFY PART B PREMIUMS

The budget proposes to gradually increase the Medicare Part B premium over a five year period from 25 percent to 35 percent of estimated program costs. This would increase the premium from $17.80 to $18.70, or 5 percent, in calendar year 1987. In addition, for third party payers (primarily States which pay the Medicare premium for their Medicaid beneficiaries), the premium would be set at 50 percent of costs. The proposed increase in income is estimated at $725 million for FY 1987.

Question. What would be the proposal's impact on beneficiaries, particularly those who fall below 100 percent and 125 percent of the poverty line? What would be the total cost per person?

Answer. The proposal would affect beneficiaries by increasing their premium payments. The annual cost per person would be $10.80 in calendar year 1987. By calendar year 1991, the annual amount of the increase would be $191 per person.

The proposal includes a "hold harmless" provision: no beneficiary's social security cash benefit would be reduced below the previous year's level as a result of the premium increase.

The Part B premium was originally set to cover 50 percent of program costs. Over time it fell to a low of 24 percent of costs in 1981. This proposal only partly reverses the trend toward greater revenue subsidization of the part B premium.

Question. What would be the proposal's impact on the States? Is this feasible in view of the proposal to cap Medicaid payments?

Answer. The proposal does double the State's cost of the Part B premium for beneficiaries who are eligible for both Medicare and Medicaid. Even with this proposal, however, wealthier States (which have the lowest Federal matching rates) would still be paying only 25 percent of the program costs for their beneficiaries, while poorer States would be paying 10 percent of program costs. At this rate, the States are still likely to find that paying the Medicare Part B premium for their eligible beneficiaries is an economically sound decision.

The Medicaid Cap is an overall limit to Federal contribution to the State's Medicaid program expenditures. The Administration believes that there is sufficient flexibility in the amount that the States curently spend to permit the level of proposed reduction in FY 1987 without any reduction to the appropriate level of services to the beneficiaries that the State believes are the most appropriate. Since the Part B premium "buys" a collection of services at a subsidized rate, it is clear that the States would be unlikely to make reductions in this area.

INCREASE AND INDEX PART B DEDUCTIBLE

The budget proposes to increase the Part B deductible from $75 to $100 in 1987, and then index the deductible to the Medicare Economic Index beginning in 1988. The proposed savings for FY 1987 are estimated to be $310 million.

Question. How many persons would be affected by the proposed increase in the Part B deductible?

Answer. Approximately 72 percent of Part B enrollees meet the current $75 deductible each year. Approximately 69 percent would fall within the $75 - $100 range. These persons would be affected by the proposed increase in the deductible.

Question. What will be the total financial impact on beneficiaries if all of your premium, copayment, and deductible proposals are implemented?

Answer. In FY 87, the total financial impact would be to increase beneficiary payments by $1.3 billion. It should be noted that the $880 million from the Part B premium increase would be spread among all Part B enrollees, and the $310 million from the increase in the Part B deductible would be spread among the 65-70 percent of enrollees who meet the current $75 deductible. The remaining $110 million comes from the proposals for (1) a home health copayment ($100 million) and (2) the payment of standard Part B deductible and coinsurance amounts on facility charges for ambulatory surgical center services ($10 million).

ESTABLISH HOME HEALTH COPAYMENT

The budget proposes to establish a copayment equal to 1 percent of the inpatient hospital deductible, approximately $5.00 in 1987, on all home health visits, except those (1) following an inpatient hospital or skilled nursing facility stay for a condition treated in the hospital or skilled nursing facility for a related condition, or (2) visits provided (SNF) after 100 visits in a calendar year. The estimated savings for FY 1987 are $100 million.

Question. How many persons would be affected by the proposed copayments on home health visits?

Answer. We estimate that in 1985 approximately one-third or about 500,000 of the Medicare beneficiaries who received home health services did so without a prior hospital or SNF stay. These are the beneficiaries who would be subject to a copayment for the first 100 home health visits.

Although beneficiaries who use home health services received an average of about 27 visits, to protect all beneficiaries against liability in cases where the need for home health care is long term, there would be no copayment after the first 100 visits.

Question. What would be the expected impact of the copayment proposal on utilization?

Answer. We would expect some minimal impact on utilization. The proposed copayment will provide an appropriate incentive for careful consideration of the necessity for home health care services by both physician and beneficiary.

Further, Medicaid would pay copayments for those Medicare beneficiaries who are also Medicaid recipients, and many

employer retirment plans and Medigap plans would pay it for the 60% or more of beneficiaries who have such coverage.

Question. If there is any negative incentive, is it appropriate to discourage the utilization of home health services at the same time patients may need such services because of earlier discharges from hospitals?

Answer. The proposal was developed to assure that a negative incentive would not exist for those patients who might appropriately require post-inpatient care through a home health agency. The proposal would not affect patients whose home health services begin within 30 days following a hospital or skilled nursing facility stay.

The proposal would also encourage the appropriate utilization of home health care services. In the past, a study performed by the General Accounting Office, followed by later study which we performed, showed that one-quarter to one-third of home health visits reviewed were either not medically necessary or were not covered under the Medicare program.

MEDICARE VOLUNTARY VOUCHERS

The Administration proposes to establish a voluntary Medicare voucher program under which beneficiaries could elect coverage under a private health benefits plan rather than Medicare. Beginning in 1987, private plans that enroll a Medicare beneficiary would be paid premiums set at 95 percent of the Medicare adjusted average per capita cost and, in exchange, would be required to provide benefits at least equivalent in value to current Medicare benefits.

Question. Could it be argued that we should gain more experience with recent initiatives with Health Maintenance Organizations and Competitive Medical Plans before we implement this voucher proposal?

Answer. Clearly, such an argument can always be made. However, we believe that a better case can be made for moving ahead today with the voucher proposal.

- When one considers the HMO demonstrations begun in 1979, we have 6 years of experience with reimbursement at 95 percent of the AAPCC.

- Our experience to date with TEFRA HMOs/CMPs indicate that plans are providing high quality services and for the most part beneficiaries are satisfied with the program.

- We believe that the expansion of capitation options is the only way to restrain both the price and quantity of services while continuing to provide high quality care.

- By allowing insurance organizations to receive capitated payments, we would be expanding the range of options available to Medicare beneficiaries. Expanded consumer choice will lead to increased competition which should help to both restrain the growth of inflation in the health care sector and allow beneficiaries to choose a plan which comes closer to meeting their needs.

IMPROVEMENTS IN THE AAPCC

Question. What research is underway on improvements in the AAPCC? What is the timeframe over which we can expect these developments to take place?

Answer. We have studies in four areas:

- Prior use adjustors to the AAPCC.

  One AAPCC formula incorporating data on prior hospital and physician use has been developed and is being tested in an HMO demonstration. Results from the demonstration should be available by the end of 1986.

  Formulas, incorporating diagnostic information from prior hospital stays are being developed. We will decide by this summer whether these formulas are promising enough to test in a demonstration project.

  In addition, a cooperative agreement at Kaiser-Portland is studying the feasibility of incorporating risk factors that relate diagnosis and medical conditions from both ambulatory and hospital records to resource use in an HMO. Results from the study are expected by the end of 1988.

- Prior receipt of SSA disability benefits.

  Work is proceeding on an adjustor based on prior receipt of SSA disability benefits, reflecting the fact that aged enrollees formerly entitled to such benefits have much higher rates of Medicare reimbursements. Revised underwriting factors incorporating prior disability should be available by December 1986.

- Measures of health status and disability.

  Persons reporting poor health or functional limitations use more health services than others. Work is underway to incorporate health status or disability measures into an AAPCC formula. We will decide by this summer whether the available formulas with functional limitations are promising enough to test in a demonstration project.

o Reinsurance

Reinsurance could protect the government or HMO's against adverse selection. Research on the design and feasibility of reinsurance schemes is now underway. A number of reinsurance and partial capitation schemes have been proposed and we are evaluating whether any should be tested.

Question. What regulatory requirements do you plan to impose to ensure that the plans will offer benefits that are adequate for Medicare beneficiaries?

Answer. The Administration's voucher bill requires that any voucher plan offer a set of benefits equal in value to Medicare. The term used in the voucher bill to describe this requirement is "actuarial equivalence". Actuaries will calculate whether or not a plan's benefit package is equal in value to Medicare. Plans have some flexibility within this requirement to adjust benefits. For example, a plan could offset the additional cost of providing hospital benefits that are more generous than Medicare's with a reduction in Medicare's unlimited home health benefits. However, this flexibility only exists within the array of Medicare covered benefits, e.g., hospital, home health, skilled nursing facility, physician, lab, etc. Thus, for example, because outpatient prescription drugs are not covered by Medicare, a voucher plan could not count the value of offering an outpatient prescription drug benefit in meeting the requirement that the plan's benefit package be equivalent in value to Medicare. We believe that the requirement that plans offer a set of benefits equivalent in value to Medicare, combined with the limitation that any flexibility in reducing some benefits to increase others is limited to benefits already covered by Medicare, will assure that the benefits are adequate for Medicare beneficiaries.

Question. Has the private insurance industry given you any indication that they will be able to provide private insurance programs to the elderly which will offer benefits equivalent to those currently offered under Medicare at a rate which will result in savings to the government?

Answer. Some insurers have expressed an interest in becoming health benefit plans. Once the voucher bill is enacted, we would expect that other companies would also be interested, especially as the health care market becomes more competitive.

In addition to insurers, some employers and unions have expressed interest in a provision in the voucher bill which would allow them to combine Medicare with their own plan to provide non-duplicative coverage to their annuitants.

DEEMED STATUS

It is my understanding that on December 24, 1985, HCFA granted deemed status to the College of American Pathologists to accredit laboratories under Medicare. Yet, on January 28, 1986 that decision was reversed.

Question. Why did HCFA reverse its decision?

Answer. The College of American Pathologists (CAP) initially was denied its request for recognition of its accreditation program for clinical laboratories on August 8, 1985. CAP requested reconsideration of its request and was approved on December 24, 1985. This approval was withdrawn on January 28, 1986 on advice of counsel and because it was felt that a reexamination of the issues involved was necessary.

Question. What is the current status of this situation?

Answer. The CAP accreditation program remains unapproved while HCFA reexamines its methodology for reviewing and approving requests for recognition of accreditation programs.

Question. What are your plans for the future in resolving this situation?

Answer. As noted, HCFA is reviewing the entire issue and a decision will be made on CAP's request in the near future.

ICF/MR - "LOOK BEHIND" SURVEYS

Your budget justification states that 800 "Look Behind" surveys for Intermediate Care Facilities for the Mentally Retarded (ICF/MRs) will be conducted in FY 1986.

Question. Would you provide for the record the breakout institution size of the 800 surveys?

Answer. Federal staff scheduled surveys in an estimated 800 ICFs/MR in FY 1986. Projected surveys by institution size is provided as follows:

15 Beds or Less	16-199 Beds	300 Beds +
391	284	125

Question. What do the survey results show? How many deficiencies warrant termination? How many deficiencies warrant plans of correction?

Answer. We are pleased to report that we have found fewer

facilities with widespread major deficiencies than we expected based on earlier investigations. The most frequent deficiencies we are finding involve inadequate program services for clients (e.g., physical and occupational therapy, speech and language therapy, psychology services) and insufficient direct care staff responsible for the protection, supervision and training of clients. Fewer deficiencies have been found in physical environment and health care areas.

In FY 85, we found 41 of 464 facilities with conditions that posed a serious and immediate threat to client health and safety. HCFA moved to terminate them immediately. Thirty-five of these facilities had problems with fire safety, but six were found to have major problems with client abuse, infection control, unsanitary conditions, and critical nursing shortages. Only 2 of the 41 facilities out of compliance were unable to make immediate corrections to avoid termination.

Thirty-one of the 464 ICFs/MR were found to have such serious and widespread deficiencies, that they were notified that if they did not correct their deficiencies or submit an acceptable plan of correction, they would be terminated from participation in the program. Of this figure, only 6 of the 31 facilities out of compliance either voluntarily withdrew from the program or were terminated.

In sum, 72 facilities surveyed were out of compliance, however, only 8 of 464 facilities surveyed withdrew or were terminated. The other 64 facilities were able to correct cited deficiencies to continue program participation. This is evidence of the responsiveness of States and facilities to our enforcement efforts.

Question. How many "look behind" surveys are you projecting for FY 1987?

Answer. We are currently projecting that Federal staff will survey an estimated 1,025 ICFs/MR in FY 1987.

Question. Given the problems uncovered in ICF/MRs through increased monitoring, do you believe this number of "look behind" surveys will be sufficient to monitor quality of care?

Answer. Facility managers across the country have experienced the seriousness of our intent to enforce Federal standards for ICFs/MR. The impact of our effort has been outstanding in terms of improving services to individuals in these facilities. Furthermore, we have gained the cooperation of facility managers and State officials in stressing compliance with Federal requirements. Our targets for FY 87 will maintain this initiative at the level necessary to ensure maintaining an adequate level of enforcement.

RESCISSION

Question. A $9,401,000 rescission is proposed for Program Management in FY 1986. Please provide for the record a breakout by category (i.e., travel, consultants, publications) and the effect on Program Management projects. In particular, please indicate any research or demonstration projects that would be reduced or foregone if this rescission were to be enacted.

Answer. The proposed rescission/deferral to HCFA's research and demonstration budget amounts to $7.332 million. As a result of this proposed rescission/deferral, HCFA will be curtailing lower priority new and expanded research and demonstration efforts that would:

- o test the feasibility and potential cost savings of geographic capitation models and voucher payment systems;
- o some of our efforts to measure differences, if any, in the quality of care provided to Medicare beneficiaries resulting from implementation of the prospective payment system;
- o study further refinements to the methodologies of prospective payment and further determine various impacts of the hospital prospective payment system;
- o develop and analyze information on health care utilization patterns and cost expenditures which would identify those factors contributing to effective program performance and would also provide a basis for a better understanding of potential program reforms.

In addition, $2.1 million was proposed to be deferred from the Medicare Contractor budget. The deferral was necessary to bring contractor funding in line with the President's budget. We believe the President's original budget is adequate to process claims, ensure program payments are made appropriately and provide above average service to Medicare beneficiaries.

RAILROAD RETIREMENT BOARD

Question. Would you provide for the record the reasons why you are proposing a language change that would prohibit obligation of funds for a separate Railroad Retirement Board contractor?

Answer. The Health Care Financing Administration has reached an oral agreement with the RRB under which the chosen carrier, Travelers, has stated that it will process claims at the national average unit cost for all carriers for FY 1987. Nevertheless, we continue to believe that RRB beneficiaries would be better served by dealing with their local carrier. The GAO has documented (in three reports; 1972, 1979 and 1984)

the large volume of misrouted claims sent to local carriers. Considerable costs are incurred by the local carrier to transmit these claims to Travelers. In addition, the RRB carrier has been deficient in implementing one of HCFA's highest priority initiatives: Medicare Secondary Payer (MSP). It is interesting to note that the RRB had used Travelers' expected proficiency with MSP collection as a rationale for retaining the contract in previous years. We estimate that elimination of the contact would result in savings of approximately $2 million in FY 1987 and eliminate confusion for beneficiaries, providers and suppliers as well as carrier and SSA employees.

RESEARCH, DEMONSTRATIONS AND EVALUATION

The FY 1987 budget estimate for research, demonstration, and evaluation is $18.5 million, a reduction of 40 percent from the $31 million appropriated in FY 1986. This amount will only fund the continuation costs of ongoing projects and will not allow for any new starts.

Question. How will you fund any new congressionally mandated studies?

Answer. We will be able to fund new congressionally mandated studies at the requested budget level by reallocating funds away from lower priority ongoing projects.

If the Congress mandates that HCFA fund new studies, an alternative would be to request a supplemental appropriation for those studies.

In particular, funding for the program area of "State Programs for Long-Term Care" is reduced from $1.6 million to $500,000, or two-thirds in FY 1987. Yet, you acknowledge in your budget justifications that "nearly 50 percent of Medicaid expenditures are for long-term care services. The growth rate is likely to continue to increase in the future, due in part to demographic trends."

Question. Given the growing seriousness of the problem, the fact that States have less Medicaid money to fund such research, and that HCFA is probably the primary organization to conduct such research, don't you think this program area requires a higher priority in your funding levels?

Answer. HCFA continues to be interested in encouraging State programs that provide alternative ways to deliver and finance long term care under Medicaid. Because Medicaid is State run, HCFA believes that actual pilot programs implemented by the State are the most direct way to address this problem. Currently, two programs, Home and Community Based Waivers and Freedom of Choice Waivers, allow States the flexibility to redesign the long term care portion of their Medicaid program. Proposals for such projects were solicited for our April 1985

and November 1985 grants and cooperative agreement review cycle via a January 30, 1985 Federal Register announcement.

The reduction in our funding for the "State Programs for Long Term Care" research program area is attributable to the completion of existing projects; consequently, those projects require no continuation funds.

Question. What assurance do you have that employer-based health insurance plans would extend private coverage for an additional month if the program's initial eligibility date were delayed?

Answer. The information available to us suggests that people currently covered under private health insurance plans would be able to continue their coverage because of the way insurance coverage is structured. For example:

- Many health plans are written to continue full benefits until the covered individual becomes eligible for payments under Medicare.

- Other plans remain in effect until the individual becomes eligible for Medicare or until the next policy renewal date following the covered individual's 65th birthday, whichever comes first. In most cases, this would leave the individual insured until he or she becomes eligible for Medicare.

- Many employment based plans will continue benefits for 30 days after the employee separates from his/her job.

- Persons leaving group health plans are generally allowed to convert to an individual policy. Thus, persons not yet eligible for Medicare can protect themselves through private individual policies.

- A number of States have laws that require plans to continue benefits and/or provide a conversion privilege to a reasonably comparable individual policy.

In addition, we believe that neither the insurance industry nor the employer community would knowingly allow people to lose all health insurance protection for such a short period of time due to a minor change in Medicare. Thus, while some plans may require an amendment to their policy provisions, we would expect all policies to coordinate their benefit packages with this change in Medicare.

Finally, the Consolidated Omnibus Budget Reconciliation Act of 1985 provides additional protections for some beneficiaries by requiring employers (except churches, Federal, State and local governments, and employers with less than 20 employees) to

offer coverage to employees for 18 months following a voluntary or involuntary termination from employment.

LACK OF HEALTH INSURANCE

Questions. How many persons lack employer-based or similar private health insurance protection at age 64 and would therefore be without coverage for an additional month?

Answer. 8 percent of persons aged 64 have neither public nor private health insurance coverage. 84 percent have private health insurance and an additional 8 percent have public coverage (Medicare, Medicaid, or CHAMPUS). For those who are poor and in need of services, Medicaid coverage is available as of their 65th birthday.

INCREASED THIRD PARTY LIABILITY ACTIVITIES

The budget proposes to: require States to collect health insurance information during the eligibility determination process; use data obtained from States unemployment agencies to identify Medicaid recipients who may have employer-related health insurance; and perform trauma code edits to identify accident-related insurance. The savings are estimated to be $100 million in FY 1987.

Question. Describe your recent efforts to improve third party liability activities. How successful have they been?

Answer. Identification of third party resources and cost avoidance are the keys to achieving third party liability (TPL) savings. HCFA has been and is working toward facilitating and enhancing the identification process. A final rule was published on November 16, 1985, which requires States to use a cost avoidance method of payment for claims processed after May 12, 1986, unless the State is granted a waiver by proving that its current method of payment is as cost effective.

HCFA has negotiated agreements with 26 States whereby SSA field offices collect detailed health insurance information from SSI applicants and provide the information to the Medicaid State agencies. This is an ongoing effort to phase in all of the 32 States ("1634 States") where SSA makes the Medicaid and SSI eligibilty determination concurrently. HCFA is in the process of surveying the participating States to determine the effectiveness of the procedure to date.

HCFA has executed agreements with all section 1634 States whereby SSA will obtain assignment of rights of payment for medical support by third parties from SSI/Medicaid applicants during SSA intake operations. The assigning of rights is a condition of eligibility.

HCFA has begun negotiations with the States whereby the Department of Defense has agreed to conduct data exchanges

through the Defense Eligibility and Enrollment Reporting System. The exchange will identify Medicaid recipients who are eligible for CHAMPUS coverage through active or retired status with the military, collect medical expenses from CHAMPUS and cost avoid future expenditures. It is too early to determine the success of this project.

In addition, HCFA published a final regulation on October 16, 1985 which requires State Child Support Enforcement agencies to petition for the inclusion of medical support in support orders for absent parents. The regulation also requires State Child Support agencies to collect information about the availability of medical support for Medicaid recipients and transmit it to State Medicaid agencies.

The $100 million in 1987 budget savings referred to in the question above will be achieved through a regulation which will implement additional mechanisms for the identification of third party resources. The following initiatives are included in the regulation:

- Requires all section 1634 States to enter into an agreement with HCFA to participate in the SSA program which collects health insurance information on SSI/Medicaid eligibles.

- In cases where the State Medicaid agency makes the eligibility determination, the State agency would be required to collect health insurance information.

- In cases where another State agency (other than the Medicaid agency) makes the eligibility determination, this agency would be required to collect health insurance information.

- Requires States to conduct data exchanges with specific State and Federal agencies:

  State Employment Security files
  SSA earnings files
  State Workers' Compensation files
  State Highway Accident files

- Requires States to use diagnosis/trauma code edits to identify accident related third party resources.

- Requires States to demonstrate effective and timely transmission of third party resource data provided by State, Federal and all other sources to the Medicaid State agency and incorporation into the eligibility file.

- The proposed regulation is currently pending clearance by the Department.

Question. How will you be able to compile the necessary records? How will you be able to keep them updated?

Answer. The compilation and subsequent updating of the records is a State function. The process to originate and maintain the data will be part of the TPL related State plan amendment changes.

MODIFY PAYMENTS FOR RETURN ON EQUITY

The Administration's budget proposes to reduce the allowance for return on equity capital for skilled nursing facilities and outpatient hospital services from 150 percent levels to 100 percent levels. The proposal would also eliminate the allowances for return on equity capital for all proprietary providers other than skilled nursing facilities and hospitals.

Question. Would this proposal force a number of skilled nursing facilities out of business?

Answer. While recognizing that proprietary skilled nursing facilities (SNFs) would be affected, we believe that the economic effect would not be significant for the following reasons. First, in addition to continuing to pay SNFs (although at a lower rate) a return on equity capital, we would also continue to pay SNFs their reasonable costs incurred in furnishing services to Medicare beneficiaries. Second, proprietary SNFs that are chain affiliates generally have access to alternative forms of financing, like issuing stocks on the open market. Finally, we believe that incentives for timely discharge from hospital care, coupled with the continued growth of the portion of the population likely to use SNF services, will tend to increase the market demand for SNF services. This trend in turn will provide sufficient incentive for interested parties to invest in the creation of new SNFs and the expansion of existing facilities.

Question. If a reduction in the number and availability of skilled nursing facilities results from this proposal, wouldn't that development contradict HCFA's drive to contain medical costs, by forcing beneficiaries to seek more expensive institutional care?

Answer. As indicated above, we do not believe the reduction in the rate of return on equity capital for skilled nursing facilities (SNFs) will result in a reduction in the availability of SNFs. Accordingly, we do not believe beneficiaries will be forced to seek more expensive institutional (hospital) care.

Questions Submitted by Senator Ted Stevens

ALASKA'S MEDICAID PROGRAM

Question: It is my understanding that the Administration proposes to consolidate and establish welfare administration matching rates at fifty percent and to cap Medicaid program expenditures on a state-by-state basis. In Alaska, we estimate the cost to the State for the reduced administrative matching rate would be approximately $1.1 million in Medicaid. An additional $3.7 million in the Food Stamp and Aid to Families with Dependent Children program is attributed to the matching rate. The estimated shortfall in Federal Medicaid program funds, if a cap is imposed, is another $3.6 million. This total reduction of $8.4 million in funding to Alaska would be a direct cost shift from the Federal government to the State.

How will these cutbacks affect the delivery of human services programs in Alaska?

Answer: The 1987 Medicaid budget request is intended to slow the rate of program growth without compromising the quality of health care for program recipients. The proposal encourages States to adopt further cost-containment measures to achieve reachable spending goals. The proposal includes additional flexibility for States to mold their eligibility coverage and reimbursement policies to deliver care more efficiently and at lower cost. In addition, several regulatory initiatives (such as second surgical opinion/inpatient preadmission review programs, use of lower cost generic drugs, and strengthening efforts to identify third party resources) should produce savings in which States will share. With these new tools, we believe that States can meet the proposed spending limits without adversely affecting delivery of services.

Historically, the Federal government has paid 50 percent of Aid to Families with Dependent Children (AFDC) administrative costs, and States have funded the remaining 50 percent. The two pending legislative proposals which relate to administrative costs do not affect this basic division of financial responsibility and would not impact on the provision of AFDC benefits. One of these proposals would limit full 50 percent matching for administrative costs to a level equal to 175 percent of the median State administrative cost per recipient. Costs above this level would be matched at a reduced rate. This proposal is designed to introduce, in a limited and reasonable way, an incentive for administrative efficiency. The other proposal would reduce the AFDC incentive matching rate for data systems development from 90 to 75 percent and set a time limit for incentive funding. However, Alaska already has completed system development, for which it received Federal funding at the 90 percent matching rate.

As the economy in Alaska faces a tight period, the state is experiencing a sharp increase in caseloads for its social service programs.

Question. Have you considered whether the increases in

public assistance caseloads in states such as Alaska, along with the accompanying increases in Medicaid program expenditures, will compound the negative affects of the cap on Medicaid expenditures?

Answer. Other factors, such as changes in the elderly or poor populations, have been considered as methods to adjust expenditures under the Medicaid cap. However, none of these factors were considered appropriate to be used to adjust future spending levels. Extraordinary variations already exist among States; current Medicaid programs in what proportion of the poor are eligible, the range of services that are covered and the generosity of provider reimbursement amounts. Given these differences, there is no simple way to make other adjustments to the Cap that do not have widely differing effects across the States.

In addition, such adjustments would suffer from severe data problems, for example, data that would be necessary is not timely, reliable, or available on a State by State basis.

The Administration is proposing a one-time "hardship fund" to help such States as Alaska if they experience high cost growth despite rigorous cost control efforts. It is expected that after this transition period, States will have developed major reforms to their programs to provide services more efficiently without any reductions in quality or service levels.

INDIAN HEALTH SERVICE

Under current Administrative procedures, IHS bills Medicaid for the cost of services provided to Medicaid eligible Alaskan Natives. Even though Federal Medicaid reimbursement to IHS is 100 percent, requiring no State match, it is not clear whether the proposed cap on Medicaid payments on a State basis will include these direct payments to IHS. If it does, then Medicaid payments to private vendors will be reduced by Federal payments to another Federal agency, and other estimated losses in Medicaid program receipts would increase.

Question. Will the Medicaid cap apply to IHS Medicaid payments for health services to Alaskan Natives?

Answer. Yes. Under current law, the Federal Medicaid program pays for 100 percent of the expenditures for services to Medicaid beneficiaries in Indian Health Service facilities. The amount paid for these claims in FY 1985 was approximately $14 million or 7/100 of one percent of total program expenditures. Total expenditures for IHS claims for Alaskan Natives was 3.3 percent of Alaska's Medicaid program expenditures. Therefore, the impact of these services on State caps will not be large.

Question. Under the Administration's proposals, will any of the payments made through the Medicaid program by IHS apply to Alaska's Medicaid caps?

Answer. No. The mechanism by which IHS distributes the funds it receives for services that IHS hospitals provide to Indian Medicaid beneficiaries has no bearing upon Alaska's Medicaid cap.

Questions Submitted by Senator Arlen Specter

Question. On March 7, 1986 I wrote to Secretary Bowen on behalf of the Pennsylvania Society for Medical Technology to urge a reversal of the decision to offer deemed status under the Medicare system to the College of American Pathologists Laboratory Inspection and Accreditation Program. It is my understanding that an offer of deemed status was made by HCFA without regard for the due process requirements of the Administrative Procedures Act. What is the status of my request?

Answer. It is true that CAP was notified by HCFA on December 24, 1985 that its request for recognition of its accreditation program for clinical laboratories was approved. However, on January 28, 1986 HCFA withdrew its approval of CAP on the advice of counsel. HCFA is reexamining the issue and a decision will be made in the near future.

ERIE CANCER TREATMENT CENTER

Question. On January 31, 1986 Senator Heinz, Representative Ridge and I wrote to Secretary Bowen requesting that HCFA staff meet with Ross Associates and members of our staffs in Washington, D.C. to discuss problems regarding the Erie Cancer Treatment Center. This cancer treatment center would be extremely beneficial to residents of Erie and other northwest Pennsylvania communities. The efforts to proceed with the plans are now being delayed by the refusal of HCFA officials in Philadelphia to clarify key issues concerning reimbursement rates. Why has HCFA refused to cooperate with Ross Asssociates? Have you determined possible meeting dates?

Answer. In a letter to Ross Associates dated November 6, 1985, our Philadelphia Regional Office (RO) indicated that the various Medicare reimbursement methodologies that might apply (e.g., prospective payment, or payment on a reasonable cost or reasonable charge basis) would depend on whether the center would operate as part of a hospital (and treat both inpatients and outpatients) or would operate instead as a freestanding facility.

Representatives of the two hospitals, and of Ross Associates

met with the Acting Regional Administrator, on January 10 1986, and one month later furnished additional information requested by the RO. Another meeting is scheduled in the near future to discuss possible reimbursement rates.

MEDICAID QUALITY

Question. In the Medicaid FY 87 budget request, outlays would be reduced by approximately $1 billion. In subsequent years, the growth in Medicaid cost would be limited to the increase in the price in the medical care sector. What impact will these cuts have on the quality of services and on the number of recipients that will be served?

Answer. We expect that the "Cap" on Medicaid will be implemented by the States in a variety of ways depending on choices that the States make. We intend to remove a number of requirements that now restrict the States' flexibility to tailor their programs to their individual needs. The resulting increase in flexibility should permit the States greater scope for improving the cost-effectiveness of their programs. It is our opinion that the FY 1987 funding level will not reduce the quality of services nor require the States to make significant reductions to those beneficiaries who are currently eligible for Medicaid.

The States have demonstrated great creativity adapting to the reductions in the Federal Medicaid payments between 1982 and 1984. The FY 1987 budget request would give the States strong incentives to continue efforts to manage their programs cost-effectively, while not putting an undue strain on the existing programs.

Question. It is my understanding that Home Health Agencies in Pennsylvania are facing severe financial difficulty because they are not being reimbursed on a timely fashion. One Pennsylvania agency, Home Care of Western Pennsylvania is currently awaiting the reimbursement of approximately $1 million. This reimbursement problem jeopardizes the services desperately needed by many senior citizens in my state, and adversely affects the local economy. What are you doing to resolve this problem? What steps have you taken to ensure that this problem does not occur again?

Answer. The implementation of a new medical review form has caused some claims processing delays at Philadelphia Blue Cross, their intermediary. The form provides medical necessity data for home health claims. To alleviate any problem, HCFA has requested the intermediary to review the form on a postpayment, rather than prepayment basis. In addition, the intermediary has provided accelerated payments to home health agencies with cash-flow problems.

Home Care of Western Pennsylvania has been given an accelerated payment of $1.1 million as reimbursement for backlogged claims. The problem was temporary and not expected to recur, but HCFA will take appropriate action if payment delays are again experienced.

Questions Submitted by Senator James A. McClure

Question. A primary reason for having a Medicare intermediary and carrier in each State is to allow those contractors to serve the local area and to be sensitive to the local needs of beneficiaries, hospitals and providers residing in those areas. I understand the Health Care Financing Administration has developed a program that establishes national standards of performance for measuring the performance of those contractors. One of those standards looks at the relative effectiveness of a contractor's audit functions while another looks at the effectiveness of the contractor's medical review activities. I understand that the current performance measurement system penalizes a contractor that does not meet your national expectation for medical review and audit. Could you comment?

Answer. First, we do not agree that there is a need for a Medicare intermediary and carrier in every State. While we require the contractors to maintain a presence in the State, there presently exists a number of multi-State Medicare contractors. While we expect our contractors to be sensitive to the local needs of beneficiaries and providers to the extent the law allows, we strive to administer a uniform national program.

Your perception that we penalize a contractor who does not meet the national audit and medical review savings ratios is probably due to the fact that we recently selected two Medicare contractor sites to compete their workloads. These competitions rose out of the authority provided to the Secretary in section 2326 of the Deficit Reduction Act of 1984. Under that provision of law, the Secretary may enter into two intermediary and two carrier agreements in fiscal years 1985 and 1986 to replace via competitions those contractors whose cost and performance over a period of time placed them in the bottom 20th percentile of Medicare contractors. To implement this provision our first step was to develop a methodology to rank the contractors. Our methodology placed emphasis on the efforts by the contractors to save program dollars by including in the formula performance on returns from audits, medical review activities and overpayment error rates. This emphasis is consistent with our well articulated policy that contractors should assure the proper expenditure of trust fund dollars by prudent and efficient management.

Replacement of a contractor is a last step. It is HCFA's practice to work with the contractors with marginally deficient

performance as measured by the Contractor Performance Evaluation Program (CPEP). This program is a yearly process whose results we use to identify areas requiring improved performance. For contractors whose performance is egregious in terms of many areas of longstanding deficient performance, replacement may be required.

Thus, in deciding which contracts should be nonrenewed and competed, the audit and medical review return ratios achieved by the contractors played a part in those decisions along with other considerations such as the magnitude and duration of performance problems.

Question. According to a recent study produced by the George Washington University, the city of Boise, Idaho had the lowest Medicare cost per capita when adjusted for age and sex of any city in the United States. Those costs ran 71 percent of the national average. The highest cost city had costs that were 165 percent of the national average. Does the contractor performance measurement system you use expect the same results for the contractor in Idaho as for the contractor where benefit costs are so high?

Answer. Yes, the Contractor Performance Evaluation Program (CPEP) requires all contractors to meet the same national minimum standards for all performance measures, including audit and medical review.

Your question implies that there is a relationship between the per capita expenditures per Medicare enrollee and the quality or allowability of the bills submitted and the costs claimed by the provider community. Further, your question implies that this relationship makes it more difficult for a contractor in a low per capita expenditure area to meet our minimum standards. We do not come to this conclusion when we review the national data. We note contractors in areas with similar demographics, and low per capita expenditures, similar to Idaho Blue Cross, have performed significantly better than Idaho and exceeded the national minimum return ratios and some contractors in areas with high per capita expenditures did not meet the return ratios.

Question. I am concerned that your performance measurement system may have perverse incentives that encourage Medicare contractors to deny claims to meet an arbitrary performance target. Such pressures could result in claims being denied just to meet a target. How do you establish these targets? Why should I not be concerned about this? I'm worried that Medicare beneficiaries may be denied services they would otherwise be entitled to.

Answer. If our only measure of the quality of a contractor's performance were the audit and medical review return ratios we would agree with your concern. The medical review and audit activities are designed to deny procedures or

costs that should be denied. Many other CPEP elements measure if our contractors are making arbitrary decisions and inappropriately denying claims. For example, to assure that our contractors make accurate medical review determinations, there is an element in the Contractor Performance Evaluation Program which samples to determine if the medical review decision was correct.

To stress the importance of correct medical review decisions we make this a critical element which means failure to meet the element places the contractor in jeopardy. Additionally, a substantial number of appeals and high reversal rate for reconsiderations and appeals or a high payment deductible or overpayment error rate would be indications of a contractor inappropriately denying claims to meet targets. In States where our contractors have high return ratios we have not had allegations that they are making arbitrary decisions in denying claims.

The targets are set so that they are obtainable by most contractors. The contractors are consulted in the development of the measurement system and it is constantly under review and revision as the program changes or conditions warrant. Additionally, it is a public process published yearly in the Federal Register.

Question. HCFA has informed Blue Cross of Idaho that the contract for the Fiscal Intermediary is being opened to other bidders. What is HCFA doing to ensure that there is no disruption in service to beneficiaries should this contract be awarded to an out-of-state contractor?

Answer. HCFA's Request for Proposal (RFP) for Idaho requires the successful offeror to coordinate the change of contractor fully with beneficiaries, providers and other affected groups. HCFA has had a great deal of experience in managing contractor transitions. In addition to carefully reviewing proposals to assure that contractor implementation plans support continuous, full service to beneficiaries, HCFA works closely with the new contractor to assure that such plans are implemented timely and correctly.

Question. Blue Cross of Idaho currently operates six regional offices to better serve beneficiaries. I understand that regulations merely require the contractor to have a "presence" in the State. Does this mean that a potential contractor could only have a phone number for beneficiaries to call or rent a post office box for written inquiries? When HCFA is deciding which contractor should be given the FI contract, do you consider such things as the availability of regional offices? If not, why not?

Answer. The RFP requires that the successful offeror base its provider relations and beneficiary services activities for Idaho within that State. Further, at least one walk-in office

for beneficiaries must be maintained with immediate computer access to files for completed bills as well as bills currently under review. The RFP specifically allows for additional beneficiary walk-in offices at the option of the bidding contractor. The successful offeror is required to maintain the same level of beneficiary telephone service as is required of all other contractors nationally; i.e., toll-free telephone lines, with strict standards for responsiveness. In addition, we have emphasized to all potential offerors that the presence we require in Idaho must be an active one to include visits to beneficiary groups and provision of fair hearings throughout the State. In making the technical evaluation of proposals for beneficiary services HCFA most definitely takes into consideration the intensity and accessability of such services.

In regard to the regional offices currently maintained by Idaho Blue Cross, our regional office indicates that services to Medicare beneficiaries by these offices is a minor activity.

Questions Submitted by Senator William Proxmire

ELECTRONIC CLAIMS PROCESSING

Question. For some time now HCFA has been encouraging hospitals to submit claims to intermediaries electronically rather than by paper. Where does this now stand? What percentage of hospital claims are processed electronically?

Answer. We continue to encourage all providers to submit electronic claims to intermediaries and carriers. In recent months, the percentage of inpatient hospital claims submitted electronically has varied between 60-65%. For February, 1986, the percentage was 60.2%.

Question. While processing costs vary from intermediary to intermediary, can you give the Committee a general idea of the comparative cost of processing a claim electronically versus paper transactions?

Answer. We estimate that an electronic claim submitted to an intermediary costs approximately $.50 less to process than a hardcopy claim. The bulk of the savings is attributable to elimination of data entry (keypunching). The balance is due to fewer errors, less paper handling, etc. We currently have an industrial engineering contract to determine a more exact differential between processing on electronic versus a hardcopy claim. The results of the study should be available by the end of the year.

Question. Does HCFA provide incentives for hospitals to make the transition to electronically processing for claims? If not, why not?

Answer. HCFA has encouraged hospitals to bill

electronically by showing that it would be mutually beneficial. Additionally, we have published a notice of proposed rule making requiring EMC from providers receiving periodic interim payments (PIP).

Question. As you know, there is great concern among hospitals that reductions in the budgets for intermediaries and carriers for claims processing will result in a general slowdown of claims processing as one way of meeting the reduced budget. Do you expect such a delay and can you outline how much of an increase in processing time you expect for both intermediaries and carriers?

Answer. Because of the mandated reductions imposed by the Gramm-Rudman-Hollings legislation, we will increase contractor days work-in-process from 9 days on Part A at the end of FY 85 to 16 days by the end of FY 86 and from 11 days on Part B to 16 days by the end of FY 86. Our FY 87 budget projects the days work in process to increase to 22 days for both intermediaries and carriers by the end of the year. This increase will basically conform Medicare payments to the provisions of the Prompt Payment Act and substantially increase interest earnings to the Medicare trust fund.

Question. If you are assuming an increase in processing time, will there be a differential between electronically and paper-processing claims? Should intermediaries give priority to electronic claims as an incentive for hospitals to convert to this system?

Answer. Because intermediaries are already allowed to give priority to electronic claims, any increase in processing time should affect electronic and hardcopy claims equally.

Question. In the Part B program, tne delay in processing claims will fall hardest on beneficiaries whose physicians have refused assignment and many of these beneficiaries will already have paid their full bill. Is it possible for carriers to give priority to patients in this position? If not, how can we assure that delays in processing do not leave these beneficiaries in a worse position than they were last year?

Answer. We do not believe that segregating non-assigned claims is equitable to our participating physicians who have agreed to take assignment on all their bills. By giving priority to non-assigned claims, we would be penalizing physicians and suppliers who take assignment thus, encouraging non-participation. Although days work in process will increase gradually to 22 days by the end of FY 87, we do not believe our beneficiaries will be severely hurt. Because we are guided by the Prompt Payment Act, beneficiaries should be reimbursed in approximately thirty days, which is common business practice.

Question. Over the years there have been numerous proposals to use electronic technology at the level of the individual physician to improve claims transactions and assure prompt, accurate payment. Suggestions have included introduction of a Medicare credit card, a so-called 'smart' card such as Blue Cross has introduced which can actually store data, and the use of electonic transmission devices in the physician's office, such as many retail operations now use to provide immediate verification of credit card transactions.

Can you outline for the Committee the degree to which carriers have employed such technology at the present time? What is the current state of knowledge regarding the costs and benefits of such technology in light of our effort to reduce the long-run costs of claims processing?

Answer. Some physicians own or lease terminals or Personal Computers and submit claims via electronic media (not necessarily transmit but send magnetic tape, disc, by mail to contractor). First quarter FY 86 figures indicate 22.7 percent carrier claims and 57.7 percent intermediary claims are filed via EMC. Our project goal at the end of FY 86: 26.1 percent carrier, 62 percent intermediary claims.

Studies have shown that the cost of plastic cards and required necessary equipment would be prohibitive for the Medicare program. Below is the appoximate cost to supply and operate carrier cards for the Medicare population:

o embossed card alone	$16,450,000
with imprinter	$80-150 per unit
o Magnetic stripe card	$17,500,000
with terminal	$150-200 per unit
with optional personal computer	$2,500 - 4,000 per unit
o Life Card (Blue Cross)	$122,500,00
IBM or compatible PC	$2,500 - 4,000 per unit
Read/write unit	$1,000 per unit
Physician software	$1,500 per package
Hospital software	$4,500 per package

Annual costs after start-up:

o embossed card	$1,410,000
o magnetic stripe	$1,500,000
o Life card	$10,500,000

All costs are not inclusive of any additional staffing necessary to initialize or maintain a new system. If use of a particular card is mandated for Medicare claims processing, the Federal Government may have to provide the necessary equipment: cost per unit would be multiplied by the number of providers/suppliers (approximately 272,953 in 11/85).

Blue Cross experiment cost/benefits cannot be approximated prior to Life Card implementation: savings depend on high usage by subscribers/providers/suppliers (usage is optional for subscribers). The Life Card is especially suited for a small controlled group for data collection and personal contact. It would be more difficult for a large dispersed population such as that of Medicare beneficiaries.

Certainly, we will continue to examine the use of all card based technology for its future use in the Medicare program.

Question. Does HCFA have any demonstrations completed, underway or on the drawing boards for evaluation of electronic claims transmission or use of credit cards or 'smart' cards by beneficiaries? Can you provide a brief overview now but a detailed summary for the record?

Answer. We are about to let a contract for an evaluation of electronic claims use. This study will compare paperless claims processing with hardcopy claims processing to determine cost differences. Results of this study will be the analytic base for planning goals and predicting dollar and burden hours savings associated with paperless claims processing. Results should be available by the end of the calendar year.

There are no studies conducted or contemplated for use of "smart" cards in Medicare claims processing. The potential exists but as was discussed it is not considered a cost-effective alternative.

A demonstration utilizing embossed plastic cards in Puerto Rico was prompted by processing problems caused by the unique custom of Hispanic double surnames. For the past year, current and new beneficiaries residing in Puerto Rico have been issued plastic Medicare cards for use with imprinting devices and carbon set billing forms. Costs/savings are currently being evaluated for this manual claims processing procedure.

Question. Can you briefly review now, and provide a more detailed report for the record, of the use of such technology by the States in the Medicaid program?

Answer. Magnetic surface stripe cards are currently used by several State Welfare Agencies for obtaining on-line computer terminal eligibility validation determinations and as a vehicle for Electronic Benefit Transfer (E.B.T.) for the U.S. Department of Agriculture food stamps program.

Additionally, several States are considering other magnetic stripe card/telecommunications options for Medicaid. The card would, at a minimum, allow a provider to use a low cost card reader to establish recipient eligibility on-line and permit day specific termination of eligibility. Third party liability determination and program utilization are also applications that are being considered.

Several States are looking at the possibility of utilizing card technology in their Title XIX process:

Early Stages (looking at possibility)
- Florida
- Louisiana
- Ohio
- Pennsylvania
- South Carolina
- Tennessee

Intermediate State (analysis completed)
- California
- Colorado
- Massachusetts

Advanced Stages (RFP being developed or has been developed)
- Illinois
- Michigan
- Minnesota
- New Jersey

The State of New York is implementing a card based system which is called Electronic Medicaid Eligibility Verification System (EMEVS). EMEVS is based on the concept that Medicaid recipients will present an encoded magnetic stripe plastic ID card for an electronic eligibility verification check at the point of service (POS).

New York State Department of Social Services (NYSDSS) currently issues a paper Medical Assistance ID (MA) card which recipients use to document their eligibility. This card, valid for the entire month of its issue, may be used by recipients to obtain services throughout the month, even if their eligibility has been terminated prior to the end of the month. Implementation of an EMEVS would allow NYSDSS to move from monthly eligibility to day specific eligibility as the EMEVS will require providers to access a daily updated statewide eligibility file to verify recipients' eligibility at POS.

Day specific eligibility can generate significant savings as the many recipients who now continue to obtain services past their actual termination date will no longer be able to do so.

In addition, those recipients who, because of system constraints, receive a valid ID card for the month subsequent to their month of termination, will no longer be able to obtain services past their termination date because of day specific eligibility. Savings from both these areas are estimated to be $17 million annually.

Question. Have any evaluations been performed by the States or HCFA on the cost-benefit of such technology?

Answer. Cost benefit analysis of this technology is not feasible because the primary implementation in New York is just beginning.

Question. One area in which this technology would seem useful is in the area of prescription drugs under the Medicaid program. While many States have attempted to curtail the abuse of having a prescription filled at several pharmacies, or a Medicaid recipient receiving multiple prescriptions from different physicians, I am under the impression that the problem still persists. In light of these problems and the tremendous paperwork involved in processing and auditing of prescription drug claims, what are the possibilities for use of this technology in this area?

Answer. This technology appears to have great potential for the legibility and claims processing areas of the Medicaid program. We especially feel that the technology, coupled with the use of generic drug coding, holds the possibility of reducing Medicaid costs in the long run. However, detailed analysis of its cost/benefit/implementation need to be performed.

CLAIMS PROCESSING

Question. To what extent is HCFA working with the States, through research, demonstration support and technical assistance, to pursue methods of lowering the cost of claims transmission and claims processing?

Answer. We provide technical assistance to States on EMC and card based technologies on an ongoing basis. Additionally, we emphasized in our 1984 Management Information System Conference, card based technology with two full sessions. We also expect to recommend to the State Technical Advisory Group that the 1986 MMIS/TPL Conference include sessions on cost saving technologies.

Question. Because of the tremendous overlap between Medicaid and Medicare and other income support programs, is HCFA working with the Social Security Administration and the Department of Agriculture on a joint approach to these problems? Please detail for the record what degree of cooperation has taken place so far and whether any formal mechanisms have been established for cooperation.

Answer. Although no formal mechanism has been established to encourage electronic transmission technology, we maintain staff-to-staff contact with Agriculture and SSA on electronic transmission issues. At this stage of development, we believe a more formal mechanism would not be fruitful. However, if experimentation leads to beneficial results, we would certainly develop a joint approach.

Question. To what extent does HCFA support efforts by intermediaries and contractors who have demonstrated cost-effectiveness in their operations and wish to make systems improvements to further reduce costs? On what types of projects have such funds been allocated in the past and to what extent does your FY 1987 budget support such productivity investments this year?

Answer. Systems improvement continues to be available for our contractors. Productivity investments which are projected to return HCFA's investment within 2 years will continue to be funded within the available budget.

One of our major initiatives is to develop a compatible computer system which will be transportable to other contractor sites. Our initial efforts in this area will be with our Part A intermediaries to be followed approximately one year later by our carrier initiative.

Question. Has there been any effort by HCFA to standardize the software used by Medicare carriers and intermediaries? Is such standardization feasible? What are the projected costs and benefits to the program of standardization in the Medicare program?

Answer. Standardization of software has proven effective throughout the data processing community. We feel confident that standardization within the Medicare community will provide the same economies of scale experienced within the private sector. An initiative is underway for FY 86 to establish the actual costs and benefits of transferring a large scale claims processing system to a pilot receiver site. We are expending about $3 million this year on the project. Savings will be evaluated based on our 1986 experience.

HOME HEALTH SERVICES

Question. My office has received repeated complaints by home health agencies that claims for services, such as physical therapy, are being denied by intermediaries on the grounds that such service should have been provided by the hospital under its DRG payment. In cases where a denial takes place on those grounds, what is HCFA's policy for recovering the costs of the rehabilitative services from the hospital?

Answer. Situations such as the one you have described do not constitute a basis for denial of home health coverage. A patient who meets the requirements for home health coverage under Medicare may receive the covered services whether or not it may have been possible for a hospital to have provided them before discharge. If there is evidence of intermediary denials on the grounds cited, we will be happy to correct the situation.

Question. Unless HCFA requires the hospital to pay the cost of these services, it would appear that the beneficiary is the loser in such a situation, provided the services are medically necessary. Has HCFA provided intermediaries with instructions on how to handle cases where the beneficiary medically needs the services but the discharging hospital fails to provide them? Is HCFA assuring that the beneficiary will not foot the bill for services to which he or she is entitled?

Answer. As noted above, there is no basis for denying home health coverage merely on the basis that services could have been provided by a discharging hospital. There should be no denials on this basis and therefore no beneficiary liability for payment. If, on the other hand, the hospital prematurely discharges a patient, a PRO sanction would be possible. Also, under a new provision in this year's reconciliation act, a PRO will be able to deny individual hospital bills when substandard care has been rendered. We would look to these provisions to discourage premature discharges.

Question. Do you believe that it continues to be useful to peg the nursing home copayment to the hospital deductible? As you know, the copayment charged to beneficiaries for the 21st through 100th day in a skilled nursing facility is now $61.50/day. Wisconsin Blue Cross responded to inquiries from my staff and reported that a number of nursing homes in Wisconsin receive payments from Medicare that are actually lower than the $61.50 copayment. It would appear that the copayment is growing so fast that the Medicare SNF benefit is becoming meaningless for many beneficiaries beginning on the 21st day. Would it not make more sense to peg the nursing home copayment to the cost of nursing homes?

Answer. We do not believe that the issue relates so much to using the inpatient hospital deductible as the cornerstone for other copayments as it does to examining the proportion of the deductible used for these various copayments. We believe that it would be appropriate for the Congress to take up this additional issue at the time it reconsiders the deductible.

Question. In cases where the nursing home copayment ($61.50) actually exceeds Medicare's payment after auditing by the intermediary, what happens to the differential? Is it returned to the beneficiary? Or is the sick beneficiary subsidizing the Medicare program? If so, are the funds deposited in the Part A trust fund?

Answer. In determining the reimbursement that is due a SNF for its accounting year, we deduct the sum of the copayments imposed on the SNF for the year from the SNF's aggregate reasonable costs for the year. We do not determine the cost of care to an individual patient. The amount of excess coinsurance is restricted, however, by the fact that Medicare has provided by regulation (42 CFR 409.85(c)) that the

amount of coinsurance per day is limited to the lesser of the SNF's actual charges per day for the services or the statutory amount of the coinsurance.

Question. What is the Administration's position on such cases? Do you support return of money to the beneficiary when Medicare's payment to the nursing home is less than the Medicare-required copayment? Or do you believe the beneficiary should subsidize the program in those cases?

Answer. We believe the rule limiting the coinsurance to the SNF charge per day protects the beneficiary against undue burden. SNFs must set charge levels reasonably related to the costs they incur in order to attract patients, and it is unlikely that an SNF's charges would be significantly greater than its costs. To change the system in a way that required a recalculation of the daily charge based on a facility's end of the year cost settlement would be administratively burdensome for the government and for the facilities and would be unlikely to produce refunds that significantly offset the effort. We would also note that the method the Congress established by law for calculation of the copayment for outpatient hospital services (copayments are based on hospital charges but the Medicare payment is related to the facility's costs) is based on the same rationale.

Question. The Administration has projected a major increase in the number of Medicare beneficiaries receiving care from Health Maintenance Organizations or Competitive Medical Plans. Since these organizations are paid on the basis of the Adjusted Average Per Capita Cost (AAPCC) formula, the accuracy of this formula will become increasingly important. Can you explain for the record how the AAPCC is constructed and the weighting attached to each of these items?

Answer. The calculation of AAPCC values that are applicable to a future calendar year is developed in four conceptually basic steps:

1. Medicare national average calendar year per capita costs are projected for the future year under consideration.

2. Geographic adjustment factors that reflect the historical relationships between the county's and the nation's per capita costs are used to convert the national average per capita costs to the county level.

3. Expected Medicare per capita costs for the County are adjusted (by removing both reimbursement and enrollment attributable to Medicare beneficiaries in eligible organizations under contract with HCFA) to a fee-for-service basis.

4. The fee-for-service Medicare cost per capita is disaggregated into its demographically defined component parts to produce a set of county AAPCC values.

The table below displays the demographic cost factors for 1986 and the standardized per capita rates of payment by State and County as published in the Federal Register, January 6, 1986, pages 512 through 548.

DEMOGRAPHIC COST FACTORS FOR 1986

AGE GROUP	MALE			FEMALE		
	INSTITUTIONALIZED	NONINSTITUTIONALIZED		INSTITUTIONALIZED	NONINSTITUTIONALIZED	
		MEDICAID	NON-MEDICAID		MEDICAID	NON-MEDICAID
PART A						
AGED						
85 & Over	2.35	2.35	1.20	2.00	1.90	1.10
80-84	2.35	2.35	1.20	2.00	1.65	1.00
75-79	2.35	2.05	1.10	2.00	1.40	.85
70-74	2.35	1.65	.85	1.90	1.15	.70
65-69	1.95	1.30	.70	1.65	.90	.60
DISABLED						
60-64	.50	1.65	.85	.65	1.[illegible]	1.20
55-59	.80	1.45	.75	1.00	1.4[illegible]	1.00
45-54	1.15	1.30	.70	1.45	1.45	.95
35-44	1.25	1.05	.60	1.60	1.35	.70
UNDER 35	1.50	.95	.55	1.70	1.20	.50
PART B						
AGED						
85 & Over	1.90	1.60	1.10	1.65	1.20	.95
80-84	1.90	1.60	1.10	1.65	1.20	.95
75-79	1.90	1.60	1.10	1.65	1.20	.95
70-74	1.90	1.45	1.00	1.65	1.20	.85
65-69	1.70	1.20	.85	1.50	1.05	.70
DISABLED						
60-64	.90	1.40	.90	1.10	1.45	1.15
55-59	1.10	1.30	.75	1.40	1.40	1.10
45-54	1.35	1.25	.65	1.80	1.35	1.05
35-44	1.40	1.05	.50	1.80	1.10	.80
UNDER 35	1.50	.95	.40	1.80	.95	.65

Question. I understand that the weightings for the components of the AAPCC have not been updated since 1975. It would appear that a review is in order immediately. The proposed National Medical Expenditures Survey, which the Administration's budget indicates will begin FY 1987, appears to offer the possibility of such an update. In the view of your actuaries, what is the value of the proposed NMES survey to the AAPCC computation?

Answer. The National Medical Expenditures Survey is planned as a comprehensive survey which will include sampling of the institutionalized and welfare population. Based on actuarial review of the intent of the survey, it appears that the sampling done for the over age 65 population could be used to update the current over age 65 demographic factors. The under age 65 population may include a very large universe of individuals, but the subgroup of Medicare eligibles will be too small to consider a valid sample.

IMPROVEMENTS IN THE AAPCC

Question. What research is underway on improvements in the AAPCC? What is the timeframe over which we can expect these developments to take place?

Answer. We have studies in four areas:

o Prior use adjustors to the AAPCC.

One AAPCC formula incorporating data on prior hospital and physician use has been developed and is being tested in an HMO demonstration. Results from the demonstration should be available by the end of 1986.

Formulas, incorporating diagnostic information from prior hospital stays are being developed. We will decide by this summer whether these formulas are promising enough to test in a demonstration project.

In addition, a cooperative agreement at Kaiser-Portland is studying the feasibility of incorporating risk factors that relate diagnosis and medical conditions from both ambulatory and hospital records to resource use in an HMO. Results from the study are expected by the end of 1988.

o Prior receipt of SSA disability benefits.

Work is proceeding on an adjustor based on prior receipt of SSA disability benefits, reflecting the fact that aged enrollees formerly entitled to such benefits have much higher rates of Medicare reimbursements. Revised underwriting factors incorporating prior disability should be available by December 1986.

o Measures of health status and disability.

Persons reporting poor health or functional limitations use more health services than others. Work is underway to incorporate health status or disability measures into an AAPCC formula. We will decide by this summer whether the available formulas with functional limitations are promising enough to test in a demonstration project.

o Reinsurance

Reinsurance could protect the government or HMO's against adverse selection. Research on the design and feasibility of reinsurance schemes is now underway. A number of reinsurance and partial capitation schemes have been proposed and we are evaluating whether any should be tested.

Question. One of the more controversial issues has been the inability of the DRGs to accurately account for "severity of illness" in its payments to hospitals. HCFA indicated in an article in the Health Care Financing Review its view that in the short-term there was the possibility of modifying DRGs with Patient Management Categories (PMCs) or Disease Staging in an effort to see whether this improved the accuracy of payment. Where does this now stand? What is the timeframe for such simulations?

Answer. The $1.2 million project to develop Patient Management Categories was completed and results published. HCFA is currently supporting over $2 million in DRG refinement research. The next project we expect to be completed is the work by SysteMetrics on disease-staging within DRGs which should conclude this summer. We now believe that DRG refinement will be an evolutionary process. Simulations performed thus far by Rand, the Center for Health Economics Research and others suggest that none of the presently developed approaches which utilize Uniform Hospital Discharge Data Set elements is capable of quickly and markedly improving the DRG system. Hence, we continue to sponsor studies which seek to use physiological measures of patient health at admission and during hospitalization as potential refinement approaches. The present set of studies will continue through the summer of 1988. Meanwhile, we will continue to consider the annual recommendations of the Prospective Payment Assessment Commission and concerns raised in response to our annual Federal Register notices concerning proposed changes in the DRG-system as mechanisms for continually refining the DRGs.

RESEARCH PROJECTS

Question. Please outline for the record a list of the research projects that will be funded under HCFA's proposed research budget.

Answer. In fiscal year 1987, HCFA will continue:

- studies designed to test systems which capitate payments for various types of services as an alternative to fee-for-service reimbursement, such as HMOs and geographic capitation (approx. $4.8 million);

- study of refinements to and analysis of impacts of the Medicare prospective payment system, with special focus on the impact to quality of care delivered to beneficiaries and access to care (approx. $4.5 million);

- improvements to existing Medicare and Medicaid data bases essential to providing information on health care expenditures and utilization patterns (approx. $2.9 million);

- demonstration efforts of competitive bidding models for provision of benefits such as durable medical equipment (approx. $2 million);

- testing alternative payment systems, including capitation, competition and prospective payment, for sub-acute care (approx. $2 million);

- studies of Medicare/Medicaid coverage issues to determine impact on treatment and service utilization (approx. $.8 million);

- studies designed to improve the existing Medicare physician payment system (approx. $.7 million);

- studies to demonstrate and evaluate the impact of preventive services and patient education efforts on health care costs and utilization (approx. $.6 million); and

- efforts aimed at evaluation of major changes in the Medicare program, such as the hospice benefit (approx. $.2 million).

Question. To what extent will this reduced funding level delay congressionally mandated reports on the implementation of the DRG system and related prospective payment issues? What percentage of HCFA's research budget is reflected in congressionally-directed studies?

Answer. The reduced HCFA funding level for FY 1987 will not impact on the current schedules for submission of the mandated prospective payment reports. Any delays experienced in submitting these reports is attributable to the complex nature of the issues being studied. The data collection and subsequent analysis of the data require substantive efforts and careful examination.

We currently estimate $5 million (or 27 percent) of the $18.5 million requested for research, demonstrations and evaluations will be committed to congressionally mandated studies.

RESEARCH PROJECTS NOT FUNDED

Question. What projects will not be funded at the proposed budget level for research that would have been funded if the funding had been held constant at the FY 1986 level?

Answer. Within the limits of HCFA's requested research and demonstration budget for FY 1987, we have funded all FY 1986 project continuations and all congressionally mandated research.

As in any research and demonstration program, there are always more worthy projects than resources. We believe the resource level requested in the President's FY 1987 budget is appropriate to carry out Administration and Congressional priorities, given the need for fiscal constraint especially under Gramm-Rudman-Hollings.

Question. If the Committee increases the research budget, what are HCFA's priorities among the projects outlined in the prior question and what would be the anticipated cost of each?

Answer. HCFA has funded all priority projects in FY 1987 within the amount of $18.5 million. As stated, additional projects have not been contemplated at this time.

MEDICARE REIMBURSEMENT

Question. Outline for the record what data HCFA has required HMOs and CMPs to provide to the Medicare program regarding costs and utilization of services provided to Medicare beneficiaries.

Answer. The data required is as follows from HMOs reimbursed on a cost basis or pre-TEFRA risk basis: total plan costs and Medicare cost; utilization of various types of services rendered to Medicare beneficiaries; and premiums and payments collected from the Medicare enrollees.

From TEFRA HMO's, the data requirements are as follows: certain utilization statistics, e.g., Medicare statistics compared to non-Medicare statistics; premium structures of the basic and high options packages offered to non-Medicare enrollees; and premiums and payments collected from the Medicare enrollees.

Question. As you know, I have introduced legislation (S. 1402) to require that hospital-based and free-standing home health agencies be reimbursed on an equal footing under

Medicare. It appears clear that the incentives for cost-shifting for hospitals which are partially reimbursed under a prospective payment system (DRGs) and the remainder of services under cost-based reimbursement are simply too strong. Do you support such a change in our Medicare reimbursement strategy?

Answer. In general, we supported the bill and stated in the July 5, 1985 final notice of the Medicare schedule of limits on home health agency costs that we are considering a change such as would be effected by this bill.

The legislation you propose was included in COBRA. We would have suggested the following two changes:

- We would have changed the effective date to "...cost reporting periods beginning after the date of enactment". Experience has taught us that changes based on the beginning of cost reporting years instead of dates of service eliminates a great deal of uncertainty, confusion and the possibility of errors on the part of both providers and intermediaries.

- We would also have deleted the phrase "...on a case by case basis." Mandating, in law, an exceptions process creates an administratively difficult system and could negate the goal of the bill.

MEDICARE REIMBURSEMENT

Question. In the Reconciliation bill, as adopted by the Senate, HCFA was directed to process all skilled nursing facility claims under a regional intermediary system similar to the system we are now introducing for home health. In light of the studies which demonstrate the variability in SNF coverage decisions, such regionalization seems to be useful. Do you support such a move? If not, why not? How does HCFA propose to eliminate the tremendous variation in coverage policy?

Answer. We believe that it would be fruitful to evaluate the regionalization of home health intermediaries before any decision to consolidate SNFs is made.

Question. In my state of North Dakota, Prospective Payment System method of reimbursement has brought major changes to the health care system. Many of North Dakota's rural hospitals are facing severe financial difficulties, and some may not survive.

Rural hospitals across the country have not benefited, for the most part, from PPS. Their lower reimbursement rate, and their increased proportion of Medicare patients, spells financial disaster.

Last year, the Committee provided $30,650,000 for Research, Demonstration, and Evaluation Projects. The Committee requested that HCFA conduct a study of the impact of PPS on rural hospitals, and complete the study by January 1, 1987. What is the status of HCFA's report on the impact of PPS on rural hospitals? When can the Committee expect the report to be submitted?

Answer. In each of our annual reports to Congress on the impact of the Medicare prospective payment system (PPS), we present information on the short run impact of PPS on rural hospitals. The specific study you refer to is currently in the planning stage. We plan to have our Rand and Brandeis research centers collaborate on the study. Rand has conducted several studies on the impact of the Medicare prospective payment system for us. On this project they will work with the Center for Health Economics Research (which is part of the Brandeis Research Center.) The Center for Health Economics Research has considerable experience in studying rural hospitals. In particular, it has been conducting studies for the reports on urban-rural issues mandated by Public Laws 98-21 and 98-369. We are confident that the research will provide important information on the problems of rural hospitals, and we will do our utmost to provide the report to the Committee in as timely a fashion as possible. However, due to the necessary time it takes to plan a relevant study and gather the required data, we do not think it feasible to deliver the full report to the Committee before late 1987.

Questions Submitted by Senator Quentin N. Burdick

HEALTH CARE IN RURAL AREAS

Question. How much of the $30 million in HCFA's research, demonstration, and evaluation projects budget is being directed to study rural areas and the problems of health care providers in rural areas?

Answer. Due to the proposed FY 1986 rescission/deferral, the expected research, demonstrations and evaluation budget is now $22 million.

Our past-years' funding commitments to study rural areas and the problems of health care provided in rural areas include our single largest research project examining the problem--the $1,000,000 University of Colorado evaluation of the Medicare swing-bed program. Through that program, hospitals with fewer than 50 beds that are located in rural areas with a shortage of long term care beds are permitted to "swing" their beds between acute and long term care as needed. The evaluation will assess the impact on: access to long term care beds in rural areas; quality of long term care in hospitals; costs of services in swing bed hospitals; program-wide costs and administrative costs.

Also, thus far, we have allocated approximately $30,000 for extramural research on sole-community hospitals; $50,000 for research on large rural teaching (regional referral centers) hospitals; and $130,000 for research to explain rural-urban hospital cost differentials. All of these studies are being performed by the Center for Health Economics Research through a cooperative agreement with the Brandeis Research Center.

In the current year, we expect to allocate an additional $60,000 for the design of a study of the long term impact of PPS upon rural hospitals. The Rand Research Center will be collaborating in this effort.

In addition to the research focused totally on rural hospital issues, it should be recognized that half of the nation's hospitals are located in rural areas. Accordingly, rural hospitals constitute about half of our entire hospital research effort, both intramural and extramural. For example, last year we prepared a Report to Congress on the Impact of Medicare's Hospital Prospective Payment System in its first year at a cost of $300,000. Also, a $480,000 cooperative agreement was initiated with the Urban Institute for Selective Analyses of PPS Impact on Hospital Behavior and $5,241,000 was awarded to Abt Associates to conduct PPS impact analytic support studies over the next 4 years. Approximately 80 percent of this work will analyze impact on hospitals.

Question. Why, when HCFA's reports are months behind schedule, are you requesting a budget for RD&E activities less than half of what was provided last year? How will HCFA continue to conduct the studies essential to effecting sound program decisions on this budget?

Answer. HCFA's RD&E budget request for FY 1987 ($18.5 million) provides sufficient funding to continue all current congressionally mandated studies (including refinement of the prospective payment system and analyses of its impact, especially on quality of care) and other existing projects which have been reevaluated and determined to be priority projects (such as those designed to explore the potential for cost savings to the Medicare and Medicaid programs through various capitated models and assessing the outcome of promoting competition among providers, and those testing alternative payment systems for subacute care). The implementation of Gramm-Rudman-Hollings has heightened an awareness that a budget constraint exists, and we have responded by carefuly examining possible research projects and funding only those most valuable ones.

SOCIAL SECURITY ADMINISTRATION

STATEMENT OF NELSON J. SABATINI, ACTING DEPUTY COMMISSIONER FOR MANAGEMENT AND ASSESSMENT, AND ASSOCIATE COMMISSIONER FOR MANAGEMENT, BUDGET AND PERSONNEL

ACCOMPANIED BY:

DENNIS P. WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PHILLIP N. HAWKES, DIRECTOR, OFFICE OF REFUGEE RESETTLEMENT

JO ANNE B. ROSS, ASSOCIATE COMMISSIONER FOR FAMILY ASSISTANCE

HERBERT R. DOGGETTE, DEPUTY COMMISSIONER FOR OPERATIONS

OPENING STATEMENT

Senator WEICKER. Next we will hear from Nelson J. Sabatini, the Acting Deputy Commissioner for Management and Assessment, Social Security Administration [SSA].

Since the Office of Refugee Resettlement is now part of the Social Security Administration, Phillip Hawkes, the Director of the Office of Refugee Resettlement, will follow Mr. Sabatini.

I want to ask one thing before you get to your statement, just so that we don't spend a great deal of time on it, depending on which position you are in.

I read in the newspaper today that there apparently is a reorganization of the Social Security Administration contemplated by the Secretary, creating a new Family Services Administration, which also includes other elements aside from Social Security.

Are you in a position to comment on that today, or is that something that is for the future?

Mr. SABATINI. I can do it very generally, and give you the intent of the reorganization that Secretary Bowen announced, and the components involved in it.

Senator WEICKER. I don't want to be unfair, in other words. This is not a policy that you are responsible for.

Mr. SABATINI. No, sir.

PREPARED STATEMENTS

Senator WEICKER. Why don't you introduce your colleagues and proceed to synopsize your testimony. Your testimony in its entirety will be included in the record along with that of Mr. Hawkes.

[The statements follow:]

STATEMENT OF NELSON J. SABATINI

Fiscal Year 1987 Appropriation Requests

Mr. Chairman and members of the Committee, I am pleased to be here today to present the fiscal year 1987 appropriations requests for the Social Security Administration and the Office of Refugee Resettlement. These requests total $26.7 billion in budget authority.

Summary of Budget Requests before the Committee

I would like to summarize the fiscal year 1987 requests before your Committee that require appropriations action.

--$500.6 million for Payments to Social Security Trust Funds. Through this account the trust funds are reimbursed for the costs of certain benefits and administrative expenses chargeable to general Federal funds.

--$963.4 million for Special Benefits for Disabled Coal Miners. These funds cover benefit payments and administrative expenses for the portion of the black lung program administered by SSA.

--$10.6 billion for the Supplemental Security Income program. This request includes SSI benefits and reimbursement to the Social Security trust funds for the administrative costs of the SSI program.

--$8.2 billion for the Assistance Payments program. This appropriation includes the Federal share of the benefit costs of the Aid to Families with Dependent Children program, and funds for State and Federal administration of the AFDC program. Child support enforcement collections are included in this account as an offset to AFDC benefit payments.

--$2.1 billion for the Low Income Home Energy Assistance Program. This program provides assistance to low income households in meeting the costs of home energy.

--$374.0 million for Refugee and Entrant Assistance. This program reimburses States for the costs of providing direct cash and medical assistance to needy refugees and Cuban-Haitian entrants, as well as English language training, vocational training and other social services.

--$4.0 billion for the Limitation on Administrative Expenses. This request

provides resources needed to administer the Old-Age and Survivors and Disability Insurance programs. It also includes funds to finance costs of certain administrative functions performed for the Medicare program by the Social Security Administration, and it includes administrative funds for the Supplemental Security Income program and several smaller activities. The trust funds are reimbursed for the administrative costs of the SSI and other nontrust funds programs through appropriations to other accounts.

Funds to pay benefits from Old-Age and Survivors Insurance and Disability Insurance Trust Funds are permanently appropriated, and therefore are not part of the budget requests before this Committee.

In this statement I would like to address two key initiatives of the Agency--improvements in service to the public and disability program reform.

Systems Modernization, Management Improvements and Service to the Public

During the past year we have continued progress on the Systems Modernization Plan, to modernize SSA's system of hardware, software and storage capacity. In 1985 we reached a significant milestone in nationwide implementation of the modernized claims system when two pilot field offices began taking claims under the new process. The modernized system includes immediate entry of application information into the automated claims system and immediate editing of that data, systems generation of completed application documents for signature, and automation of most claim computations. An additional 18 pilot offices are now testing the software for the new system. Phasing in of offices will continue throughout this year and SSA will begin to realize workyear savings from it in fiscal year 1987.

In recent years SSA has reduced employment and at the same time improved service to the public through efficiencies achieved from management initiatives and increased automation of work. In fiscal year 1985 SSA's full-time equivalent usage declined by about 2,200 from the fiscal year 1984 level. We also reduced our rate of overtime usage because of the moratorium

on processing continuing disability reviews which was in effect during FY 1985, and because we received many fewer inquiries related to taxation of benefits than were anticipated in the budget. During that period we served increasing OASI, DI and SSI beneficiary populations while at the same time we reduced our workload backlogs significantly and improved claims and hearings processing times. For example:

- o Overall average processing time for SSI aged claims declined to 10.8 days in the last quarter of fiscal year 1985, an improvement of 5.5 days compared to the last quarter of FY 1984. Processing time for SSI blind and disabled claims declined to 57.7 days in the last quarter of fiscal year 1985, from 71.4 days at the end of fiscal year 1984. Likewise, RSI claims processing time improved from 23.4 days to 21.4 days, and DI claims processing time improved from 70.7 days to 66.0 days.
- o SSA processed the bulk of the 190 million 1984 annual wage reports 2 months earlier than the prior year's processing time.
- o We completed adjustment of Social Security benefit payment amounts to include 1982 earnings, and made adjustments for 1983 earnings with improvements in timeliness and degree of automation. The adjustment for 1983 earnings was completed 5 months earlier than it had been for 1982 earnings, which means that beneficiaries received increases in their checks 5 months earlier.
- o In the field offices, the number of initial disability insurance claims pending declined by more than 10 percent from 260,000 to 233,400, and the number of SSI aged claims pending declined by 51 percent from 12,500 to 6,100.
- o In the program service centers we have reduced the number of retirement and survivors insurance claims pending by 6.8 percent from 91,800 to 85,600; and in the Office of Disability Operations we have reduced the number of initial disability insurance claims pending by 26.6 percent from 48,500 to 35,600.

We will continue to improve our procedures and work processes in fiscal years 1986 and 1987 so that we can better serve the public and at the same time gradually, through attrition, reduce SSA workyears and employment. Some

examples of planned improvements and/or changes budgeted to save workyears and improve service in 1986 or 1987 are:

- o Implementation of the automated claims process which will make the Social Security claims-taking more efficient and more accurate.
- o Expansion of district office final authorization of initial claims to include cases currently referred to the program service centers for final authorization.
- o Increase in the amount of annual wage reports which are received on magnetic media rather than on paper.
- o Increased automation in support of the present SSI and RSI claims systems, and in several postentitlement activities.
- o Modernization of SSA's telecomunications network to speed up processing of claims and beneficiary inquiries.
- o Replacement of outmoded hardware in the processing centers which is used to process claims and provide management information.

Implementation of the Disability Benefits Reform Act of 1984

On January 6, 1986 SSA resumed processing periodic reviews of the continuing eligibility of disability beneficiaries after a moratorium of 21 months, during which time legislation was enacted and regulations were developed to improve policies and procedures in the disability programs administered by SSA. The cornerstone of the revised continuing disability review (CDR) process is a new medical improvement standard which establishes criteria to be applied in determining whether a person's disability continues. Individuals will continue to receive disability benefits if current medical evidence shows no improvement in their ability to work since they were last evaluated. This and other changes required by the Disability Benefits Reform Act of 1984 (P.L. 98-460) lay the groundwork for the administration of a fair, compassionate and nationally uniform disability program.

Other new rules for the disability program include:

- o Updated criteria for evaluating mental impairments. The new standards are designed to determine more realistically the ability of persons with mental

impairments to function in a competitive work environment, and they were written with the help of the professional community. Also, the new criteria require a more intensive review of each case, including reviews by qualified psychiatrists and psychologists. This year we will be reviewing, under the new criteria, 185,000 mental impairment cases denied since enactment of the Disability legislation in October 1984.

- o Evaluation of the combined effects of all of an individual's impairments in determining whether the individual has a severe impairment, rather than the effects of each impairment separately.
- o Continuation of benefits through the appeals process to the administrative law judge level, if elected by individuals who have been notified of medical cessation decisions.

The Balanced Budget and Emergency Deficit Control Act of 1985

Before concluding my remarks I would like to address the effects of the Gramm-Rudman-Hollings Balanced Budget and Emergency Deficit Control Act of 1985 on SSA's 1986 budget. The legislation explicitly exempts OASDI benefits, SSI payments and AFDC grants from reduction. Although automatic benefit increases in the black lung program are not exempt, there is no increase in 1986, so there is no reduction.

The Low Income Home Energy Assistance program and the Refugee program are not exempted and therefore are subject to a 4.3 percent reduction.

Because of the flexibility given to grantees in the energy program, it is impossible to forecast the specific effects of sequestration on individual households. In the Refugee program, the reduction will be accomplished primarily by reducing the period for Federal reimbursement of State cash and medical assistance to refugees from 36 to 31 months.

Resources available for Federal administrative expenses are also reduced by 4.3 percent in 1986. In no case do we expect this to result in reductions-in-force or furloughs.

In SSA's largest administrative account--the Limitation on Administrative Expenses (LAE)--resources budgeted for the Disability State Agencies, which determine the existence and continuation of disability, are exempted from sequestration. Reductions to meet the requirements of the Gramm-Rudman-Hollings Act have been taken in overtime and nonceiling workyears, the contingency reserve and other objects of expenditure, including automated data processing and telecommunications expenses. We do not anticipate that this action will result in any significant diminution of service to the public. Should the reduction in overtime lead to rising backlogs or processing times, consideration will be given to tapping the contingency reserve to increase workyears.

The administrative budget reductions will require some "belt-tightening", but we do not expect that they will impair delivery of program services to any significant degree. SSA will continue to carry out its initiatives in support of the Agency's four major goals:

- o to provide timely and accurate payment of benefits,
- o to administer the program efficiently and effectively,
- o to provide courteous, sensitive and dignified service to the public, and
- o to strive toward a positive work climate for all employees.

Payments to Social Security Trust Funds

The appropriation request for Payments to Social Security Trust Funds totals $500,555,000 and covers four general Federal fund payments to the Social Security trust funds.

Military Service Credits

The request before this Committee for Military Service Credits in FY 1987 is for $368,917,000. This includes the estimated amount of employer-employee OASDI payroll taxes for calendar year 1987 payable on the deemed wage credits of military service personnel. It also includes an adjustment for 1983 actual

wage credits. The payment has the same effect on the trust funds as if the deemed wages had been taxed as covered wages.

The request does not include funds for the cost of gratuitous wage credits granted for military service performed prior to 1957. Annual payments for this purpose were replaced by a lump sum payment under the terms of the Social Security Amendments of 1983, with adjustments to occur every 5 years beginning in 1985.

Special Payments to Certain Uninsured Persons

The second requested payment of $69,394,000 is to reimburse the Old-Age and Survivors Insurance trust fund for special benefits paid during FY 1985 to certain uninsured persons aged 72 years and over. The payments are made to individuals who did not have a chance to work long enough under Social Security to become insured. These beneficiaries, a declining population, were not eligible for regular monthly Social Security benefits, primarily because they retired before enactment of the Social Security Act or before their occupations were covered under Social Security.

The FY 1987 request for Special Payments to Certain Uninsured Persons is $20,870,000 below the FY 1986 estimate. The population receiving special payments is a closed group of very aged persons which declines annually. As of September 30, 1985, 32,000 persons were receiving benefits chargeable to the general funds under this provision as compared to 40,000 a year earlier.

Reimbursement for Pension Reform Administrative Costs

The third requested payment is for $744,000 to reimburse the Old-Age and Survivors Insurance trust fund for the general Federal funds share of the cost of administering pension reform responsibilities assigned to the Social Security Administration under Public Law 93-406, the Pension Reform Act. The reimbursement is for the cost of furnishing information on deferred vested pension rights to pension plan participants or their survivors. The FY 1987

estimate for pension reform administrative costs reflects a continuation of SSA's FY 1986 pension reform activities.

Unnegotiated Checks

The fourth and final requested payment of $61,500,000 is to reimburse the trust funds for the value of benefit checks that remain uncashed after 6 months, plus interest. The Social Security Amendments of 1983 provided for reimbursements based upon estimates developed jointly by the Departments of Health and Human Services and Treasury until a system capable of identifying the exact number and amount of uncashed benefit checks is implemented by the Treasury Department.

In FY 1985 a Joint Treasury/Health and Human Services study of uncashed Government checks was completed. The Departments of Health and Human Services and Treasury agreed on the amount of adjustments for FY 1983 and FY 1984, as well as a preliminary transfer for FY 1985 based on the results of the joint study. The additional prior year requirements arising from the joint determination were funded from available prior year unobligated balances.

The determination for FY 1984 unnegotiated checks exceeded available unobligated FY 1984 balances. The balance was partially funded from the FY 1985 appropriation. It was also necessary to use $11.5 million of the FY 1986 appropriation to completely fund FY 1984 unnegotiated checks. Since FY 1986 unnegotiated checks are still estimated at $50 million we have included in our FY 1987 appropriation request $11.5 million to fully reimburse the trust funds for the estimated FY 1986 requirements. The estimate for FY 1987 unnegotiated checks is $50 million.

Special Benefits for Disabled Coal Miners

This FY 1987 appropriation request for Special Benefits for Disabled Coal Miners totals $693,437,000 and is financed from general revenues. This is in addition to the $270,000,000 which Congress provided last year as a FY 1987 advance appropriation to fund first quarter benefit payments. Therefore, the

total FY 1987 appropriation is $963,437,000. It includes $957,000,000 for FY 1987 benefit payments and $6,437,000 for administrative costs. It does not include reimbursable work done for the Department of Labor, which is budgeted for by that Agency.

Program Authorization

The black lung program is authorized by title IV of the Federal Mine Safety and Health Act of 1977, which provides for payment of monthly cash benefits to coal miners who are totally disabled because of pneumoconiosis, commonly referred to as black lung disease, and to widows and certain other dependents of miners who were entitled to these benefits or whose deaths were due to this disease.

Responsibility for Administration

The Social Security Administration is responsible for processing and paying claims for miners' benefits filed from December 30, 1969 through June 30, 1973 and claims for survivors benefits filed through December 31, 1973 or within 6 months after the death of a miner or widow already on the beneficiary rolls maintained by SSA. SSA pays benefits and maintains the beneficiary rolls for the lifetime of all persons who filed with SSA during its jurisdiction.

Since June 30, 1973 SSA has continued to take miners' claims--but as an agent of the Department of Labor, which is responsible for adjudication and payment of these claims. Costs incurred by SSA in taking these claims are reimbursed by the Department of Labor.

The beneficiary rolls for which SSA has responsibility will continue to decline gradually in years to come as a result of the death of miners and the death or remarriage of widows. At the midpoint of FY 1987, 273,000 beneficiaries will be receiving monthly benefits. This is a decrease of 18,000 from the 291,000 beneficiaries who will be receiving payments at the midpoint of FY 1986.

Explanation of Change for FY 1987 Request

We estimate benefit payment obligations to be $957,000,000 in FY 1987--$35,000,000 less than in FY 1986. The President's budget estimates assume a 3.0 percent increase in black lung benefits beginning January 1987.

The decrease in total benefits is due to a reduction of $50,000,00 for the lower number of black lung beneficiaries, a reduction of $2,000,000 for slightly lower average monthly payments for beneficiaries in current pay, and a reduction of $1,000,000 for the legislative proposal, incorporated in appropriation language, to round benefits consistent with the manner in which title II benefits are computed. These reductions are partially offset by an increase of $18,000,000 due to the effect of the projected January 1987 benefit increase of 3.0 percent.

Our budget request of $6,437,000 for FY 1987 black lung administrative expenses is $198,000 higher than the current estimate for FY 1986. This is primarily to restore the Gramm-Rudman-Hollings reduction of $280,000 taken in FY 1986 but not in FY 1987.

Advance Appropriation

The budget request includes an advance appropriation of $252,450,000 for the first quarter of FY 1988. This is $17,550,000 less than the amount requested last year for the first quarter of FY 1987 because of the declining beneficiary population. This request ensures that benefit payments will continue without interruption into the next fiscal year.

Supplemental Security Income

The Supplemental Security Income (SSI) appropriation provides funds through direct cash assistance to eligible aged, blind and disabled recipients to help finance their basic needs. The appropriation request for FY 1987 is $8,230,068,000 in addition to the $2,339,250,000 already appropriated for the

first quarter of FY 1987, to bring the total appropriation to $10,569,318,000. This includes $9,589,000,000 for Federal benefits to aged, blind and disabled recipients; $8,200,000 for beneficiary rehabilitation services; and $972,118,000 for payments to the trust funds for administrative costs. Also requested is $2,765,000,000 as an advance appropriation for SSI benefits in the first quarter of FY 1988.

Federal Benefit Payments

The SSI program ensures a minimum monthly level of income to eligible aged, blind and disabled individuals. An individual's income, resources and living arrangements are evaluated to determine the actual amount of SSI payment. Payments are delivered through monthly benefit checks.

The average monthly number of SSI recipients of Federal benefits is projected to increase from 3,813,000 in FY 1986 to 3,912,000 in FY 1987, an increase of 99,000. This increase is due to projected growth in the number of blind and disabled SSI recipients, partially offset by a slight decrease in the projected number of aged SSI recipients.

The FY 1987 request for Federal benefit payments is $9,589,000,000 or $704,098,000 higher than the FY 1986 level. This increase is needed to fund:

--The 3.7 percent cost-of-living increase projected for January 1, 1987 and

--The projected increase in the number of blind and disabled recipients.

Beneficiary Rehabilitation Services

SSA provides funds to reimburse vocational rehabilitation agencies for costs incurred in successfully rehabilitating SSI recipients and in instances of discontinuation of benefits prior to completion of vocational rehabilitation. We estimate that $6.2 million will be required for vocational rehabilitation in FY 1987. This is $1 million more than the FY 1986 level. In addition, we are requesting $2.0 million (the same amount as in FY 1986)

for the referral to treatment and monitoring of participation of SSI recipients with drug or alcohol dependency.

Payments to the Trust Funds for Administrative Costs

The SSI and Social Security programs are administered on an integrated basis for purposes of economy and efficiency. The Social Security Act authorizes advances from the Social Security trust funds to pay the administrative costs of the SSI program through the Limitation on Administrative Expenses account. The advances are fully repaid from the SSI appropriation. SSA maintains a detailed cost allocation system, which has been audited by the General Accounting Office, to ensure that the trust funds are made whole (with interest, if appropriate) for the administrative expenses of the SSI program. The FY 1987 request for this activity is $972,118,000.

Advance Appropriation

The budget request includes an advance appropriation of $2,765,000,000 for the first quarter of FY 1988. This request insures that benefit payments will continue without interruption into the next fiscal year.

Assistance Payments

The Assistance Payments appropriation provides funds through grants to States to pay for the Federal share of State-administered cash maintenance assistance payments to needy families with dependent children who are deprived of parental support due to death, incapacity, absence or unemployment of a parent. Although the Social Security Administration is responsible for the programs covered by this appropriation, no trust fund money is used for assistance payments purposes.

The appropriation request for FY 1987, which reflects $236,742,000 in savings from proposed legislation, is $6,009,478,000. This is in addition to the $2,193,754,000 which Congress provided last year as a FY 1987 advance

appropriation to fund first quarter grants to States. Therefore the FY 1987 appropriations total $8,203,232,000. The total includes $8,168,331,000 for maintenance assistance; $2,925,000 for research and evaluation; and $31,976,000 for Federal administrative expenses.

At this time we also are requesting an advance appropriation of $2,293,615,000 to fund first quarter FY 1988 grants. This request also reflects savings from proposed legislation. The advance appropriation will provide funds in FY 1987 for issuing advance grants for the first quarter of FY 1988. Such a procedure enables States to continue program operations without interruption and to plan in advance.

Maintenance Assistance

The FY 1987 request for the Federal share of the maintenance assistance activities, is $8,168,331,000. The request includes:

--$6,825,863,000 for the Federal share of Aid to Families with Dependent Children (including a reduction for offsetting child support collections of $417,000,000 and a reduction for offsetting fiscal liabilities of $777,200,000).

--$13,368,000 for assistance to aged, blind and disabled adults in Puerto Rico, Guam and the Virgin Islands; the Supplemental Security Income program does not cover these jurisdictions.

--$81,900,000 for the Federal share of emergency assistance to needy families with dependent children.

--$1,239,584,000 for the Federal share of State administration and training.

--$6,616,000 for administration and training costs in Puerto Rico, Guam and the Virgin Islands.

--$1,000,000 for assistance to repatriated U.S. Nationals returning from foreign countries who have been certified by the Department of State as destitute or ill.

The FY 1987 request for these maintenance assistance activities is $790,966,000 lower than the FY 1986 level for the same activities. This decrease is the net result of several factors of decrease and increase, primarily in the AFDC and State administration and training costs activities. Significant decreases in the Federal share of costs result from the following factors:

--A net decrease of $237 million from the FY 1986 level as a result of savings from legislation proposed for enactment in FY 1987. The major proposals would require States to gradually increase participation of employable adult AFDC applicants and recipients in Job Search and other work activities, achieving a 75 percent participation level in FY 1989; and would improve the targeting of AFDC benefits, primarily by excluding the needs of an employable parent from the AFDC benefit calculation when the youngest child reaches age 16, and allowing benefits for the essential person only when such recipients are necessary to allow the caretaker relative to work or are necessary because the caretaker is incapacitated.

--Increased savings of $777 million from the collection of fiscal liabilities from the States for error rates exceeding the congressionally-mandated targets for the FY 1981 through FY 1985 reporting periods.

--Increased savings of $31 million in Child Support Enforcement collections resulting from changes in mandatory State practices and the new incentive structure provided by the Child Support Enforcement Amendments of 1984, and the Federal income tax refund offset program established by the Omnibus Budget Reconciliation Act of 1981.

Significant increases in maintenance assistance are:

--AFDC increases $171 million as a result of economic and demographic factors including: an increase in average benefits due to inflation which is reflected in higher State standards of need; an increase in the number of families headed by females, a major factor in the AFDC caseload; and an offsetting decrease in the unemployment rate.

--Federal reimbursement for State and local administration increases by approximately $241 million. Out of this total, $200 million result from the increased State administrative workloads to implement the Administration's work opportunities legislative proposal. These costs are offset by savings of $252 million in AFDC benefits generated by this proposal. Other increases in State and local administration are caused by increases in the AFDC caseload and an increase in State payroll costs.

Research and Evaluation

We are requesting $2,925,000 for research and evaluation grants and contracts under sections 1110 and 1115 of the Social Security Act, an increase of $126,000 over the FY 1986 level. The aim of these projects is to improve the management of the AFDC program and to assess policies which promote work experience for recipients and thus reduce welfare dependency. Although most of the money is for research and demonstration projects related to the AFDC program, some of the funds are used for Social Security and SSI extramural research grants and contracts.

Federal Administrative Expenses

The FY 1987 request includes $31,976,000 for Federal administrative expenses, a decrease of $497,000 from the FY 1986 level, and 585 full-time equivalents, a decrease of 50 from FY 1986. An increase for mandatory costs such as the costs of within-grade raises and promotions is more than offset by decreases in workyear requirements resulting from reduced Federal staffing for overhead and management functions.

Low Income Home Energy Assistance

The Low Income Home Energy Assistance Program (LIHEAP) appropriation provides funds through grants to States and Indian tribes to enable them to provide assistance to low income households in meeting the costs of home energy. The FY 1987 budget request is for $2.1 billion for this purpose. This is a continuation of the level appropriated by Congress for the FY 1986 program prior to the $90.3 million Gramm-Rudman-Hollings sequester order. We believe this amount will provide a reasonable level of assistance to meet program needs while supporting the President's efforts to reduce the deficit.

Authorization of the program under the Low Income Home Energy Assistance Act of 1981 expires at the end of FY 1986. Legislation will be proposed to reauthorize the program $2,100,000,000 for FY 1987.

Program Grants

We are requesting $2,097,642,000 in FY 1987 to provide grants to States, Indian tribes, and other jurisdictions to aid low income families through payments to eligible households and energy suppliers. States and Indian tribes use this assistance primarily for heating but may also use it for cooling and low cost weatherization. The FY 1987 request will continue program activities at the current level.

Federal Administration

The FY 1987 request includes $2,358,000 for funds to enable the Social Security Administration to administer the energy block grant to States, Indian tribes, and other jurisdictions. The FY 1987 request is for 32 full-time equivalents. Administrative activities include review of State and Indian tribe applications and amendments, issuance of grants, compliance and monitoring reviews, financial management functions, and preparation of the annual report to Congress. The $2,358,000 represents a $219,000 increase from the FY 1986 level. This increase is due primarily to the additional costs of

contract activities necessary to prepare reports to Congress, update the allocation formula and other program activities. It also reflects increases in personnel compensation, including step increases and career ladder promotions.

Limitation on Administrative Expenses

The Limitation on Administrative Expenses is a request for authority to spend up to $4,011,373,000 in FY 1987 from the trust funds for administrative expenses of the Social Security Administration. From this account we pay for administration of the old-age and survivors and disability insurance programs, the supplemental security income (SSI) program for the aged, blind and disabled, Medicare work performed by SSA and certain other work. For reasons of economy and efficiency SSA has integrated administration of both trust fund and some nontrust fund programs. The Social Security Act authorizes payment of SSI and certain other nontrust fund administrative expenses from this account, with full reimbursement from general funds in other accounts.

Of the new 1987 budget authority requested:

--$1.2 billion is for administering the old-age and survivors insurance program,

--$1.4 billion is for the disability insurance program,

--$142.3 million is for SSA's Medicare support functions,

--$952.6 million is for administering the SSI program,

--$76.1 million is for processing annual reports of earnings,

--$33.9 million is for annual SSA purchase contract payments on buildings previously constructed under the purchase contract method of financing, and

--$160 million is for a contingency reserve.

Included in the first five activities is $225.4 million in budget authority for automatic data processing and telecommunications activities and $760 million for the Disability State Agencies.

Contingency Reserve

For approximately the last 20 years, Congress has approved a contingency reserve for SSA's basic administrative budget account, the Limitation on Administrative Expenses. The reserve enables SSA to make a rapid response to process increased workloads not anticipated in the budget estimates, for automation projects and their impact on the workforce, and to meet mandatory increases in costs of Disability State Agencies. The $145 million contingency reserve appropriated in FY 1986 was reduced by $6.2 million to $138.8 million as a result of the Balanced Budget and Emergency Deficit Control Act of 1985, also known as the Gramm-Rudman-Hollings legislation. SSA is asking that the contingency reserve be increased in FY 1987 to $160.0 million.

The request for a contingency reserve of $160 million is necessary primarily because of continued uncertainties about the costs of administering the disability program. Disability program administration is undergoing significant change as a result of the Disability Benefits Reform Act of 1984. The cornerstone of this Act is a requirement that continuing eligibility for disability benefits be determined on the basis of a medical improvement standard. This ensures that no one is removed from the disability rolls unless their medical condition has improved, or certain exceptions are met. The Act also requires new criteria for evaluating mental impairment, and it introduces other new criteria for evaluation of disability.

The new medical improvement standard was not published in the Federal Register until December 6, 1985, and the new mental impairment regulations were published only a few months earlier. Reviews of continuing eligibility for disability benefits under the new standards began in January 1986. Previous to this time there has been a moratorium on continuing disability reviews.

For this reason the Social Security Administration had no experience under the new regulations when the FY 1987 budget was formulated. We have no base of experience, for example, about how much time it will take the Disability State Agencies to make determinations of continued eligibility for disability

benefits under the new standards, how much medical evidence will have to be purchased for mental impairment cases, or to what extent appeals of decisions will require reconsiderations and Administrative Law Judge hearings. Although we have made budget estimates, these estimates could be wide of the mark. To ensure sufficient resources are available if needed, we request the Congress to authorize a $160 million contingency reserve for FY 1987. If we don't need to tap the reserve we will not do so, and no outlays from the $160 million will occur for this. If we need it, the reserve will be available.

Automatic Data Processing (ADP) and Telecommunications

The FY 1987 request for new no-year budget authority for ADP and telecommunications is $225.4 million. However, we estimate that we will obligate $340.0 million in FY 1987, which reflects the carryover of unobligated funds from prior years, as well as a proposed change in FY 1987 to broaden the definition of telecommunications costs which are included in the no-year earmark. We are proposing to include lease, maintenance and voice communication costs in addition to the costs of telephone equipment purchases now included in the earmark. After adjustment for the definitional change, ADP and telecommunications budget authority decreases by $5.9 million in FY 1987 from the FY 1986 level, although estimated obligations increase by $18.5 million.

This level of funding in FY 1987 will provide for SSA's continued progress in modernizing its systems hardware and software as well as for the Agency's ongoing systems costs, and it will provide needed flexibility for funding the acquisition of telephone systems. We have made significant improvements in SSA's systems which permit us to provide better service to the public. For example:

--We've upgraded the capacity of the telecommunications system. On-line access to beneficiary records such as the Social Security master beneficiary record (MBR) and the supplemental security record (SSR), are now available to SSA personnel to answer questions from beneficiaries more quickly and more completely.

--We began pilot testing a new computer-aided, claims taking process in two field offices. This was the first step in modernizing the claims system to improve its efficiency.

--We posted the bulk of 190 million 1984 annual wage reports 2 months earlier than the prior year's processing time. This permitted SSA to make accurate, more timely benefit payments and to avoid overpayments.

--We completed the Automatic Earnings Reappraisal Operation (AERO) for 1982 and 1983 earnings. The 1983 AERO was completed 5 months earlier than prior AERO's. This permitted SSA to adjust beneficiary checks more quickly for higher benefits due to earnings after retirement.

Some major projects budgeted for FY 1987 are:

--$66.9 million for modernization of the SSA telecommunications network that connects all field offices, program service centers and data operations centers with our central computer facilities. This will permit faster processing of claims and beneficiary inquiries by more of our employees who serve the public directly.

--$34.5 million for acquisition of new telecommunications host processors needed to handle the expanding telecommunications workloads from our field offices.

--$6.1 million is needed to complete replacement of outmoded hardware in our processing centers in order to modernize the systems that process claims, make payments, and track cases.

--$10 million to continue conversion of all files from tape to disk storage to permit faster access to information.

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Disability State Agencies

The budget request includes $760.0 million for the Disability State Agencies in FY 1987, an increase of about $19 million over the $741.2 million budgeted for FY 1986. This reflects increases in workloads and medical costs. Some examples of principal State agency workloads for FY 1987 are:

--To process 1,631,000 new claims for disability, a decrease of 36,000 claims from the level in FY 1986.

--To process 478,200 continuing disability reviews (CDR's), an increase of about 131,000 over the level in FY 1986.

--To process over 720,000 reconsiderations of both new claims and CDR's, an increase of about 107,000 over the FY 1986 level. The increase in reconsiderations is due primarily to resumption of the CDR process in FY 1986. The increased costs are related to more face-to-face reconsiderations of CDR's, which are expected to be more time-consuming than reconsiderations of new claims involving only review of a paper record.

The State agency budget request includes $242.9 million for purchase of medical evidence of record and consultative examinations, an increase of $12.9 million over the level in FY 1986.

Federal Staffing

SSA's total workyear needs are based on projections of the workloads to be processed and how much time it will take to process those workloads. To achieve its overall workyear needs, SSA will continue to rely on a mix of full-time equivalents (FTE's), nonceiling employment and overtime workyears. For this account, SSA is requesting 78,580 workyears for FY 1987, a decrease of 433 workyears from the FY 1986 level of 79,013 workyears. We plan to achieve FY 1987 workyears with 73,270 FTE's, 1,786 workyears of nonceiling employment (principally summer youth employment), and 3,524 workyears of overtime.

The amount of overtime and nonceiling employment increases in FY 1987 from the FY 1986 level by a total of 2,466 workyears. There are two reasons for this. First, we are restoring overtime and nonceiling workyears to their previous levels after taking much of the Gramm-Rudman sequestration in this area in FY 1986. Second, in a period when our productivity is increasing, we plan to use overtime to assist in making an orderly transition to a smaller workforce.

FTE's decrease in FY 1987 from the FY 1986 level by 2,899. SSA is able to reduce workyears and FTE's in FY 1987 from the FY 1986 level primarily because of management, procedural and systems improvements which are either planned or underway. For example, in FY 1987

-- an estimated 439 workyears of savings of will result from the new automated claims-taking process, which was first piloted in two field offices in FY 1985 and which will begin to be phased in throughout this year. The automated title II claims-taking process will include immediate data entry and editing, and systems generation of application documents.

-- an estimated 146 workyears of savings by automating the process to offset an individual's initial retroactive Social Security benefit for periods in which he or she received SSI benefits.

-- additional FTE savings will be achieved through the streamlining of SSA staff functions and increasing the number of annual wage reports received on magnetic media.

These and other changes will enable SSA to improve its service to the public and provide that service more efficiently.

Statement of Phillip N. Hawkes

Mr. Chairman, members of the subcommittee, I appreciate the opportunity to discuss the refugee and entrant assistance program of the Department

of Health and Human Services and the budget that we are proposing for FY 1987.

Title IV of the Immigration and Nationality Act and Section 501 of the Refugee Education Assistance Act of 1980 (Public Law 96-422) authorize a comprehensive program of cash and medical assistance and social services for refugees and Cuban and Haitian entrants. Funding for the program has been provided by a series of continuing resolutions since the authority to make appropriations expired at the end of fiscal year 1983. By the close of fiscal year 1985, 49 States, the District of Columbia and Guam had approved State plans for refugee resettlement. In addition, 33 States and jurisdictions currently provide assistance and services on behalf of Cuban and Haitian entrants.

The FY 1987 budget request of $373,998,000 for refugee and entrant assistance is premised on Congressional reauthorization of the refugee program with certain proposed modifications.

The modifications we are proposing would consolidate into the Refugee and Entrant Assistance account the share of assistance costs formerly funded through the AFDC and Medicaid Programs. In addition, the period for which full reimbursement of refugee assistance costs is available to States would be limited to an initial resettlement period of eighteen months. We believe that discontinuing the treatment of refugees and entrants on the basis of categorical eligibility will result in a more uniform policy of cash and medical assistance and foster a more intensive program of State-administered services aimed at achieving refugee and entrant economic self-sufficiency.

The new policy would alter the funding mechanism for refugee cash and medical assistance without changing the level of assistance available to resettling refugees and entrants. Those refugees who would otherwise be

eligible for categorical assistance (AFDC and Medicaid) would continue to receive benefits under the refugee program at least equal to the comparable categorical benefits.

Funding is also requested for three activities in addition to the State Administered Programs. They are Preventive Health, Voluntary Agency Programs and Federal Administration. No funds are requested in FY 1987 to support refugee/entrant educational assistance or programs of targeted assistance. We have also requested that all funds appropriated in 1986 for Targeted Assistance and for Education Assistance be rescinded. Funds already provided have resulted in building educational capacity adequate to meet childrens' needs. In the case of Targeted Assistance, nearly $300 million have been expended in what was conceived as a short-term program of impact aid. In the context of Federal deficit reduction, these are areas where we believe Federal costs should be reduced.

In summary the four activities proposed for FY 1987 are briefly as follows:

1) State Administered Programs. We are requesting $356,560,000 under this activity to provide Federal funds for special cash and medical assistance provided under State administered programs to eligible refugees/entrants and for employment-related social services. The funds cover the entire cost of special cash and medical assistance for refugees/entrants during the first 18 months in this country, including the cost of States' supplementation of federal SSI benefits and the cost of services to refugee/entrant unaccompanied minors. Related State administrative costs are fully reimbursed as well.

Funding for refugee social services is included in the State Administered Programs request at a level of $46,803,000. This amount is $2,001,000 above the 1986 level under the proposed rescission. Funding under continuing resolutions over the past several years has fixed the level of

social services resources in the face of a continued decline in numbers of arriving refugees with the result being that social services resources are now substantially in excess of need.

2) Preventive Health. We are requesting $10,355,000 to support two basic functions related to health care for refugees. First, funds will be made available for monitoring the adequacy of medical screening and assuring appropriate follow-up and treatment of refugees with diseases of public health concern. This work will be conducted by Centers for Disease Control (CDC) personnel stationed overseas and at ports of entry. They will work to assure the continued high quality of medical screening and disease surveillance overseas and inspection and State notification procedures at ports of entry. They will also continue to operate a computer system for refugee medical records and a tracking and notification system for refugees with class A/B tuberculosis, class B venereal disease, and class B leprosy.

The budget request also includes funding to cover a modest grant program to support State and local health agencies which conduct health assessments and immediate follow-up care for a variety of conditions including skin infections, intestinal parasites, malnutrition, and anemia. In addition, this activity will provide support to State and local health departments for follow-up and preventive treatment of refugees found to have tuberculosis infection.

3) Voluntary Agency Programs. For FY 1987, ORR proposes to decrease the Federal matching payment to voluntary agencies to $250 per refugee to further stimulate greater private sector financing. This program originated to provide additional funding for an alternate initial resettlement approach for Soviet and East European refugees during a period of unusually high arrival rates in 1979 and 1980.

The voluntary agency program is not intended as a program to supplement State-administered assistance but is an alternative program to provide national voluntary resettlement agencies with matching Federal funds for resettlement assistance and services for refugees. The principal objective is to enable the refugees to become self-supporting and independent members of American society. The essential services required are case management, job placement, and maintenance support for up to four months, as needed. Additional services which may be provided include English Language Training, medical assistance, and acculturation.

Funding is provided for this activity in lieu of regular State administered cash and medical assistance and social services. We are requesting $1 million for this program activity.

4) Federal Administration. The Office of Refugee Resettlement (ORR) was established by the Refugee Act of 1980 to be responsible for the management of the domestic refugee resettlement program.

We are requesting $6,083,000 for this activity. These funds are used to administer the annual appropriation for refugee and entrant assistance, to monitor the recipients of Federal grants under the Refugee Resettlement Program and the Cuban/Haitian Entrant Program, both fiscally and programmatically, and to continue national initiatives (such as planned secondary resettlement, alternative programs for cash and medical assistance, English language training and employment standards) in response to the problems of domestic resettlement.

I wish to thank you for the opportunity to address this subcommittee. I am prepared to respond to questions at this time.

Biography of Nelson J. Sabatini

Position: Acting Deputy Commissioner for Management and Assessment since May 1983, and Associate Commissioner for Management, Budget and Personnel, Social Security Administration since February 1982.

Former Positions:

Executive Assistant to the Commissioner of Social Security, 1981-1982

Deputy Director, Office of Disability Programs, Social Security, 1979-1981

Executive Officer, Office of Operational Policy and Procedure, Social Security, 1979

Assistant Bureau Director, Bureau of Supplemental Security Income, Social Security, 1976-1979

Executive Officer, Office of the Associate Commissioner for Field, Social Security, 1975-1976

Assistant Executive Secretary, Office of the Secretary, Health and Human Services, 1974-1975

Various administrative and field positions, Social Security, 1962-1974

Education: Lewis College, B.A. - Psychology, 1958-1962

George Washington University - Graduate studies in ADP and Administration

Awards: Presidential Rank Award, 1984
Commissioner's Citation (SSA), 1981
Commissioner's Citation (SSA), 1977
Secretary's Certificate (HHS), 1975

Personal Data: Born in Rochester, New York on January 20, 1940; Married, 2 children.

Biography of Phillip N. Hawkes

Phillip N. Hawkes, Ph.D., 46 was appointed director of the Department of Health and Human Services' Office of Refugee Resettlement on June 9, 1981.

Hawkes, a long-time resident of Sacramento, California, spent three years in military service. Leaving the Army in 1960, he went to work for the Aerojet General Corporation while attending school. At Aerojet, he was a production control supervisor in the research and development program for Titan and Apollo Rocket engines. In 1970, Hawkes received his Ph.D. in anthropology from the University of California, Davis and became professor of anthropology at California State University, Sacramento until 1980.

During his tenure as professor, Hawkes also served as a consultant to utility companies, the U.S. Forest Service, etc., to facilitate effective communication, conflict resolution, and policy direction with community interest groups and Indian tribes.

In February 1981, Hawkes was appointed by Health and Human Services Secretary Richard S. Schweiker as his special assistant for refugee affairs. On April 18, 1981, he was appointed acting director of the Office of Refugee Resettlement and confirmed as Director in June, 1981.

The Office of Refugee Resettlement administers HHS's refugee assistance program, which pays the costs of providing cash assistance, medical assistance and social services to refugees, and carries out a wide variety of discretionary activities designed to develop and test more effective ways of resettling refugees and reduces impacts and costs to communities which have received large numbers of such immigrants.

INTRODUCTION OF ASSOCIATES

Mr. SABATINI. Mr. Chairman, I am pleased to be here today to present the fiscal year 1987 appropriations request for the Social Security Administration, and the Office of Refugee Resettlement [ORR].

With me at the table are Mr. Phillip Hawkes, Director of the Office of Refugee Resettlement, and Ms. Jo Anne Ross, Associate Commissioner for Family Assistance. Representing the Department of Health and Human Services is Mr. Dennis Williams, the Acting Deputy Assistant Secretary for Budget. Mr. Herbert Doggette is also with me, and Mr. Doggette is the Deputy Commissioner for Operations at the Social Security Administration.

Upon conclusion of my remarks, Mr. Hawkes would like to make a brief statement concerning the budget request for the Refugee Program.

OPENING REMARKS

Our request before the committee totals $26.7 billion in budget authority for the following accounts:

Payments to the Social Security trust funds, special benefits to disabled coal miners, supplemental security income [SSI], assistance payments, low-income home energy assistance, refugee and entrant assistance, and the limitation on administrative expenses.

Funds to pay benefits from the old age, survivors, and disability insurance trust funds are permanently appropriated and, therefore, are not part of the budget request before this committee.

I would like to mention two initiatives that the agency has undertaken designed to improve service to the public, and also an initiative related to the Disability Reform Act.

During the past year, we have continued our progress on the system modernization plan. This plan is designed to modernize our systems of hardware, software, and storage capacity. In 1985, we reached a significant milestone in nationwide implementation of the claims modernization system when two pilot field offices began taking claims under the new process. The phasing in of offices will continue throughout this year, and we will begin to realize work-year savings from this effort in fiscal year 1987.

In recent years, SSA has reduced employment and at the same time improved service to the public through efficiencies achieved from management initiatives that have increased automation of work. At the same time, we served increasing OASI, disability income, and SSI beneficiary populations, while we have reduced our workload backlogs significantly, and improved claims and hearings processing times.

For example, average processing time for Social Security and SSI claims and hearings in the last quarter of fiscal year 1985 had improved by at least 6.6 percent, and as much as 33.7 percent compared to the last quarter of fiscal year 1984. We processed the bulk of 190 million 1984 annual wage reports 2 months earlier than the prior year processing time.

We completed an adjustment of Social Security benefit payment amounts to include earnings for calendar year 1982 and 1983 with improvements in timeliness and the degree of automation.

We will continue to improve our procedures and work processes in fiscal year 1986 and fiscal year 1987 so that we can better serve the public, and at the same time gradually, through attrition, reduce SSA work-years and employment.

On January 6, 1986, we resumed processing periodic reviews of the continuing eligibility of disability beneficiaries, after a moratorium of 21 months. During this period, legislation was enacted and regulations were developed to improve policies and procedures in the disability program administered by the Social Security Administration.

The cornerstone of the revised continuing disability review process is a new medical improvement standard. Under this standard, unless certain exceptions are met, individuals will continue to receive disability benefits as long as current medical evidence shows no improvement in their ability to work since they were last evaluated.

OPENING REMARKS—GRAMM-RUDMAN

Before concluding my remarks, I would like to address the effects of the Gramm-Rudman-Hollings Act on our 1986 budget.

As you know, this legislation explicitly exempts all OASDI benefits, SSI payments, and aid to families with dependent children [AFDC] grants from reduction. Although automatic benefit increases in the Black Lung Program are not exempt, there is no increase in 1986, therefore, there will be no reduction.

The Low-Income Home Energy Assistance Program [LIHEAP] and the refugee program are not exempted from sequestration and, therefore, are subject to the 4.3-percent reduction.

Resources available for Federal administrative expenses are also reduced by 4.3 percent in 1986. The important point to make, though, is that we have found ways to absorb this reduction without having to resort to reductions in force or furloughs.

Our largest administrative account, the limitation on administrative expenses, also contains resources budgeted for the State disability agencies [SDA's]. These are agencies that make the determination of the existence and continuation of disability, and funding for them is exempted from sequestration under the Gramm-Rudman-Hollings bill.

The reductions that we have taken to meet the requirements of the Gramm-Rudman-Hollings bill have been taken in overtime, and non-ceiling work-years, the contingency reserve, and other objects of expenditure, including automated data processing [ADP] and telecommunication expenses.

We do not anticipate that this action will result in any significant diminution of service to the public. Should this reduction in overtime lead to rising backlogs or increased processing time, we will consider tapping the contingency reserve to reduce the work-years necessary to maintain an adequate level of service.

While these reductions will require some belt-tightening, we don't expect that they are going to seriously impair the delivery of our program services to any of our beneficiaries.

RESPONSE TO SENATOR SPECTER'S LETTERS

Senator SPECTER. Mr. Chairman, could I ask one question?

Senator WEICKER. Certainly.

Senator SPECTER. Thank you, Mr. Chairman.

Mr. Chairman, I appreciate the opportunity to say a word at this moment because I have other commitments. I have some questions to submit for the record, but I would make one comment at this point.

My questions refer, in part, to two letters which I have sent to the Secretary, one on January 31 and one on March 7 of this year. While there hasn't been an opportunity probably for you to reply to the March 7 letter, I think that there has been an opportunity to reply to the January 31 letter.

There is a current problem which many Senators face on letters to the Department heads. We realize how busy you are, but to the extent that you could try to be just a little bit prompter on responses, it would be enormously helpful. This is especially true with your Department, which touches so many people and on so many, many lives.

When people contact Senators, we filter them, and send you a very, very small number of the ones which come to us, but when we deem it important enough to write to you, we would appreciate it if you could pay a little closer attention on a prompt response.

Mr. SABATINI. Senator, we will find those two letters and see to it that the response comes very quickly.

I would also like to mention that Secretary Bowen, from the first day that he came into the Department, has made it very, very clear that he expects congressional correspondence to be taken very, very seriously. He has started a major initiative to make sure that it is handled promptly, that we are responsive, and that you get timely responses.

So I think that your concerns are shared, especially by the Secretary, and I think that you will see improvements.

Senator SPECTER. I am delighted to hear the policy, and now I am looking forward to the implementation.

Senator WEICKER. Thank you, Senator Specter.

OPENING REMARKS ON REFUGEES

Mr. SABATINI. Mr. Chairman.

Senator WEICKER. Yes, Mr. Sabatini.

Mr. SABATINI. Mr. Hawkes would like to make a brief statement.

Mr. HAWKES. Mr. Chairman, we are requesting a total of $374 million for the refugee program in 1987, which includes several changes. The most important would be to reduce the 100-percent reimbursement program which is currently at 31 months to 18 months.

In addition to this proposal, we would also like to treat refugees who are eligible for these programs under the rules of the Refugee Cash As-

sistance Program rather than the rules of the mainstream AFDC Welfare Program. It has become increasingly clear over the last 5 years that in many areas of the country the AFDC Program does not meet the needs of refugees, and that it is at least in part responsible for the growing number of refugees on public assistance.

In our 1987 request, we have not requested funds for targeted assistance, nor for education aid for refugee school children. Both of these programs were seen as temporary startup programs. Targeted assistance was made available first in 1982. Since that time, we have distributed $243 million, based on the numbers of entrants and refugees that arrived in this country in 1980, 1981, and 1982. Over the last year, we have conducted a number of site visits on targeted assistance programs and found that for the most part they tend to be getting jobs for refugees who are already employable, or at least potentially employable, but they leave unserved a vast number of refugees who are on public assistance and who show no immediate signs of, or any progress toward, getting off that program.

We don't believe that the funds are being well spent, and we believe that $243 million is enough out there for a program that is now serving people that have been in the country for 6 years or more.

Along with our 1987 request, we are requesting three rescissions in our 1986 budget. One would be to eliminate targeted assistance for the reasons just stated. A second would be to reduce social services from $69 million, which is the number under Gramm-Rudman, to $45 million, which was the level in the President's 1986 budget request. This $69 million figure is a holdover from being under a continuing resolution for the last 3 years. Sixty-nine million dollars would be the correct amount if we still had something like 400,000 refugees that have been in the country 3 years or less. This year there are only 200,000 refugees in that category, and we believe that the $45 million requested is adequate to provide social services for those people.

Finally, we are proposing to eliminate educational aid for refugee school children. That money was first appropriated in 1981, and it was to cover the startup costs of school districts that had no experience in dealing with Indo-Chinese refugee children. A great deal of money has been distributed under that program. Since most resettlement is currently family reunification, refugee school children are currently going to school in districts with up to 10 years of experience in dealing with them.

We believe that these three proposed rescissions are good management, and also in line with budget reductions.

Thank you.

LONG-TERM STAFF REDUCTIONS

Senator WEICKER. Your budget recommends a further reduction of 3,000 Social Security staff in fiscal year 1987 on top of the 1,000 full-time positions cut in fiscal year 1986. But nowhere do I see any mention of the 5-year plan announced last year to cut 17,000 full-time equivalent positions.

Do you still anticipate a reduction of 17,000 staff-years by fiscal year 1990 as a result of the systems modernization plan?

Mr. SABATINI. Senator, the 17,000 reduction has been cast in the past as a plan that we are asking approval for. Unfortunately, those numbers were interpreted as being numbers that had been carved in granite.

The 17,000 reduction is a target that represents a 20-percent reduction in the size of the agency staff that we expect we can derive through improvements in productivity and changes in our process, including the modernization of our systems.

The plan that caused a great deal of controversy and a lot of debate last year is not being reflected this year. We are saying that this is an out-year target that we are striving for, yet we are planning to look at these numbers on a yearly basis as we go through the budget cycle to make sure that we can detail exactly what improvements we can anticipate, what the magnitude of those improvements will be, and we plan on dealing with those goals and that target on a yearly basis.

Senator WEICKER. So we can throw that 17,000 figure out, really. It doesn't really relate to very much of anything.

Mr. SABATINI. I think that it relates to a direction.

Senator WEICKER. I can understand announcing a plan that you are going to try, if circumstances permit, to achieve every year further savings by virtue of computerization, or whatever, but I don't see how you can get that figure.

Mr. SABATINI. It is a figure that is consistent, I think, throughout the administration. It is a figure that is consistent and is reflected in the management report that accompanied the President's budget submission. This is a desire or a goal to say that, over a given period of time, we will attempt to realize 20 percent in savings.

The details of that, we are working on each year through the budget cycle.

Senator WEICKER. In your particular case, the constituency served is becoming larger very rapidly. I have sat here and received testimony from the National Institute of Aging that this population is increasing.

SERVICE TO A GROWING BENEFICIARY POPULATION

Mr. SABATINI. There is no question that the population is increasing, but the characteristics of that population are changing dramatically as well.

Today's retiree, in terms of level of education, sophistication, and the ability to deal with institutions, and deal with institutions in different ways, compared to the constituency that we served 20 or 30 years ago, is dramatically different. The type of service and the needs have changed dramatically. I think we are recognizing that, and we are looking at ways to provide the kinds of services that meet their needs.

While the population is growing, the growth in our work is primarily for people who have established their entitlement and are on the rolls. The level of effort and the type of work activity involved in maintaining the rolls is dramatically different from establishing eligibility.

The elderly population today, in large part, can deal with or conduct its business by telephone, and through other vehicles, in ways which enable us to achieve efficiencies in our process.

I think the thing that we have to be very careful of, and the thing that we are striving to avoid, is to establish a mediocre level of service, or an average level of service. We have to recognize the different needs of the population we serve, and be able to provide the services that are tailored to meet those needs, and that is exactly what we are doing, Senator.

Senator WEICKER. We are talking about an additional 3,000, and last year it was 1,000, and you are picking up, the staff tells me, 1 million more people in fiscal year 1987 than you had in fiscal year 1986. You are picking up 1 million additional, and you are cutting back 3,000.

Mr. SABATINI. But, Senator, we have been looking very carefully over the last several years at the way we do business and the things that we do, to see if they can change, improve, and be made more efficient.

Our beneficiary rolls have continued to grow, while at the close of this fiscal year, the agency will be approximately 8-percent smaller than it was 5 years ago. By the same token, by every measure we have—the level of service that we are providing today, if you look at the status of our workloads, our backlogs, and things like that—we are in better shape today than most of us who have been with the agency a long time can remember.

GAO REPORT ON SERVICE TO THE PUBLIC

Senator WEICKER. According to a GAO report, 25 percent of the clients reached Social Security offices only after three or more calls. One-third of the clients visiting local offices had to wait 30 minutes or more to be served. Thirty percent of the SSI recipients rated the services fair to poor.

Mr. SABATINI. To some extent, this reflects some problems that we have had with telephone technology. We are now in the midst of an ongoing cycle to take a look at all of the telephone equipment we have, and we are changing the telephone equipment to bring in state-of-the-art equipment that will deal with that problem.

We have also taken several other actions designed to deal with problems that we have in telephone answering, and I think that you will see marked improvement in that, and some of that has already manifested itself.

AFDC DISALLOWANCES

Senator WEICKER. Your fiscal year 1987 budget assumes that you will collect $777 million from sanctions imposed on States due to error rates in some of the AFDC programs. Yet the House and the Senate appear near agreement on reconciliation legislation that would impose a 2-year moratorium on AFDC sanctions.

Once this legislation is enacted, will you submit a revised budget request?

Ms. Ross. Mr. Chairman, you are correct that the House has recently passed the reconciliation bill which provides for a 2-year moratorium on AFDC disallowances. This has been an issue of great debate, as you are also very well aware, for the last 2 years.

The Department moved ahead in making the decisions for the fiscal year 1981 disallowances. We made the budget estimate for collection of the disallowances in the same way as has been done for the past several years, which is to use our best estimate of when we would be able to collect the disallowances, and to use the total potential disallowance amount in the budget. We have no basis for assuming other than full collections since we don't know exactly how many States will get waivers and for what dollar amounts.

FISCAL YEAR 1987 REFUGEE BUDGET

Senator WEICKER. Let me move on for a minute to the refugee area.

The budget proposes to finance refugee cash and medical assistance directly from the "Office of Refugee Resettlement" account, and eliminate the source of funding through aid for dependent children and Medicaid. Second, the period of funding will be reduced from 36 to 18 months.

Will ORR continue to reimburse the States for the cost of general assistance programs for refugees who qualify under them for the second 18 months after their arrival?

Mr. HAWKES. No, sir; we wouldn't propose to do that. We would make it an 18-month program with no extension of funding benefits beyond that period.

Senator WEICKER. What are your plans for funding refugees who do not categorically qualify for AFDC or Medicaid in months 19 to 36 after their arrival?

Mr. HAWKES. They would be eligible for the same general assistance programs available to other residents of a State. That is the situation that currently prevails in the States that don't have general assistance programs, at the end of 18 months, there are no specific services available for refugees beyond those that are available to the general population.

We think that, with the modifications in the program that we would be able to make under an RCA model, we could reduce the number of refugees who pass that 18-month mark without becoming employed.

Currently under the Gramm-Rudman-Hollings budget reduction, we have reduced the program from the 36 months to 31 months. We think that there is a tendency in some States to allow refugees to more or less find their own speed during that period. Federal funding does very little to pull people out of mainstream programs, set up special programs or find special employment opportunities for them as long as their costs are 100 percent federally funded. By shortening that period, we think that we can get more attention focused on refugees at the State and local levels, as well as the Federal level.

Senator WEICKER. How do you propose to change the period of full reimbursement to States from 36 to 18 months?

Mr. HAWKES. We have proposed that in legislation, and it is also part of the budget submission.

Senator WEICKER. If the legislation doesn't pass, how much more money would be required to carry out the 36 months fully?

Mr. HAWKES. Senator, I don't have that information.

Senator WEICKER. Would you submit that, for the record, because I have some doubts that it is going to pass.

Mr. HAWKES. Yes, sir.

[The information follows:]

If required legislation isn't passed, the Office of Refugee Resettlement will require less funding than the current fiscal year 1987 request to carry out a 36-month program. This results from the fact that under a 36-month program, AFDC and Medicaid will have to pay for their normal Federal share of costs (their costs for refugees in the country 18 months or less are in ORR's fiscal year 1987 request). The reduction to ORR's budget would be:

Transfer back to AFDC for the normal Federal share of title IV–A benefits—reduction	$48,742,000
Transfer back to Medicaid for the normal Federal share of title XIX benefits—reduction	30,237,000
Increased ORR costs due to increase in period of eligibility from 18 to 36 months—added costs	(30,438,000)
Total reduction for ORR	48,541,000

Thus, ORR's fiscal year 1987 budget would be $48,541,000 less than the current request of $373,998,000 (or just $325,457,000). However, title IV–A's budget would have to be increased by $48,742,000, and title XIX's by $30,237,000. The effect to the administration's fiscal year 1987 budget submission would be a net increase of $30,438,000, if ORR were required to carry out a 36-month program.

CONCERN OVER STAFFING CUTS

Senator WEICKER. I have further questions for the record. I want to say this. I am going to be watching this, if indeed you get your cut, and it depends, I suppose, on the actions of the full committee, but I am deeply concerned over this next cut in relation to the increase in the constituency. Of course, if we get into a crunch, there is no way to reverse it. I want to express those concerns at this hearing.

I think also what I ought to request is a GAO evaluation of this cut as it proceeds, so that by the time that we see you next year, we will have something in hand. If indeed, it isn't working out the way you are projecting it, then we had better think of some other alternatives.

Mr. SABATINI. Senator, we have said all along that we are going to strive to make some reductions in the size of the agency. But there is a commitment within the administration that those reductions are not going to come at the expense of service to the public.

EFFECT OF BUDGET REDUCTIONS ON THE ELDERLY

Senator WEICKER. My problem in this whole area, I have to tell you right now, I didn't want to exempt Social Security. I thought that Social Security should be there with everything else, but my more political

compatriots, both on the Republican and Democratic side, both in the House and the Senate, and in the White House, decided that we are going to do this, and that, in effect, sends a signal to the elderly Americans that everything is OK.

I will also use this occasion to say that everything is not OK. In order to achieve that exemption, among many other programs, I have had witnesses come before me from the National Institutes of Health indicating that we had to cut back on Alzheimer's research, that we had to cut back on the training of doctors to go into geriatrics, that we had to cut back on housing for the elderly—this is another subcommittee, not mine.

If indeed, the impression is being given to the elderly that everything is OK, I would suggest that what is going to happen with this policy is that they are going to reach Social Security age, and they are going to collect their Social Security check, and they are not going to have any quality of life at all when that happens.

So, so much for the administration's commitment to the elderly. I think in this instance, it is, very frankly, a very misleading commitment, both by the administration and my congressional colleagues who did the same thing. They just took the most visible symbol of care for the elderly, and said, OK, we are going to exempt that, but we won't tell anybody about what else is going on, and one of those things that is going on is to cut back in personnel, which could impact on constituency. I am not ready to dispute that point with you yet, I want to have some harder evidence in hand before I do, but it is certainly a possibility considering the numbers being cut relative to the increase in the constituency that you serve.

I only wish I were sure in the sense of my ground, but I am not, but I certainly will be as I watch this next 3,000 cut take place, if indeed Congress permits it.

I notice that my good friend Senator Chiles is here. I am sure that he has a few questions to ask in both of these areas.

EXPLANATION OF DEFERRAL REQUEST

Senator CHILES. Thank you, Mr. Chairman, I appreciate that.

The report of the conference agreement for Social Security appropriations for fiscal year 1986 states that:

> The conferees are agreed that the funds provided shall be used to support an employment level at Social Security Administration at 73,340 full-time equivalent positions, an increase of 1,000 over the number requested by the President's budget.

It is now clear that in fiscal year 1985, the report has been violated by maintaining full-time equivalent level at the level of the President's budget rather than the level that Congress stipulated, and this has nothing to do with Gramm-Rudman.

Independent of the announcement of the Gramm-Rudman sequester order by the President, you sent a deferral message to the Congress requesting the funds for the 1,000 positions that Congress required be deferred until March 30. Thus, for the first half of the year, you had no

intention of proceeding with the higher staffing levels, even in the absence of Gramm-Rudman. You are setting the levels where you want, congressional report language notwithstanding.

I wonder if you would tell us why you have chosen to ignore the congressional report language regarding the full-time equivalent staffing levels even before Gramm-Rudman went into effect?

Mr. SABATINI. Senator, we looked at our resource levels and what our resource needs would be in order to make sure that we provided a good level of public service. At the beginning of the fiscal year, we were convinced that we would not need the additional 1,000 FTE's that were included in the committee's report.

Upon making that decision, we thought that it was the right thing to do, and the legally proper thing to do, to inform the committee of our decision, and ask the committee and inform the committee that we were going to be deferring the expenditure of those funds.

When Gramm-Rudman came along, that $30 million was needed to help us meet the reductions necessary for sequestration under Gramm-Rudman, and that $30 million has now been sequestered under Gramm-Rudman and, in effect, has been taken out of deferral.

Senator CHILES. In effect, you anticipated Gramm-Rudman even before it came out. You figured that you were going to take these funds, and you are not going to comply with the congressional report.

Mr. SABATINI. We did not need the additional 1,000 FTE's, to the best of my judgment at that point in time. Therefore, we decided that we would defer that expenditure, and we so informed the committee.

Senator CHILES. It seems like sometimes there is some congressional role under the Constitution that Congress plays. It appropriates the money. It designates how the moneys will be spent. Do you think that at any time the Department is going to say, "We don't care what Congress asked, or what they said, we think something different."

Mr. SABATINI. Those roles are very clear. Once Congress appropriates money, there are only three things that you can do. You can either spend it, rescind it, or defer it. In compliance with the statute, our feeling was that we didn't need that money at that point in time, and that we wanted to defer the expenditure of these funds.

UPDATE ON LONG-TERM FTE REDUCTION PLAN

Senator CHILES. Last year, the President proposed a staff cutting of 17,000 slots over 5 years. This year, the administration indicates that the President's budget proposes the same reduction plan, and it is going to reduce the staffing positions, you claim, without reducing service to Social Security clients, and that this can be achieved through automation, and improved management and efficiency.

I think the facts sort of belie these words. We know that OMB ordered you to cut 17,000 positions by 1990. What scares me is that it is already clear that some of these proposed efficiencies will never materialize, however, you have not changed your target of cutting those 17,000 positions in the Social Security Administration.

I have a memorandum from the Social Security Administration, this is not the final memo, but it is very close to the final memo, which says, "The initial plan for the staff reduction includes a 2,000 person cut associated with service delivery changes, recognizing that this is not a realistic estimate." This is no panacea, however, since the bottom line reduction remains at 17,000.

In other words, after you had made the decision that you cannot achieve any of the 2,000 person cut in the original plan, you did not lower your overall target to 15,000, but you kept it at 17,000.

Why does the President's budget submitted this year continue the same 17,000 staffing cut even though you dropped out the saving of 2,000 positions in your so-called streamlining service delivery?

Mr. SABATINI. The 17,000 reflects what we think is a goal, what we have identified as a goal for achieving a 20-percent reduction in the size of the agency through improved processing and efficiencies, including improvements coming as a result of our systems modernization.

SLIPPAGE IN SYSTEMS MODERNIZATION PLAN

Senator CHILES. You have indicated installation of the computers had been delayed beyond the start of fiscal year 1987. Have you made any adjustments for that?

Mr. SABATINI. Our fiscal year 1987 budget reflects a very small, a very modest reduction coming from the systems modernization effort. There has been some slippage and some delay. We are looking at the extent of that to see if we can make some of that up.

Senator CHILES. You are showing a saving of 439 work years.

Mr. SABATINI. For fiscal year 1987.

Senator CHILES. As a result of systems modernization.

Mr. SABATINI. This is moderate. We are going to try to assess the magnitude of the slippage and see what impact, if any, that it will have on the 1987 request.

Senator CHILES. Will you inform us of what you find?

Mr. SABATINI. Yes.

Senator CHILES. Mr. Chairman, I have some other questions, which I will submit for the record.

Senator WEICKER. I will indicate to Mr. Sabatini that if the Congress approves the reduction that they have requested this year, I intend to have a GAO report track the effects on the services of such a reduction.

Senator CHILES. Thank you.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. I have further questions for response to the record. Thank you very much.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

Budget Request

Question. Mr. Sabatini, what was the Social Security Administration's original FY 1987 budget request to the Department? What was the Department's request to OMB?

Answer. The following chart shows SSA's budget requests to the Department and to OMB for FY 1987:

Budget Summary
(appropriation request in thousands of dollars)

	SSA's Request to the Department FY 1987 Estimate	Department's Request to OMB FY 1987 Estimate
Payments to Social Security Trust Funds	*	$497,988
Assistance Payments	*	$8,983,613
Low Income Home Energy Assistance	$2,188,000	$2,188,165
Supplemental Security Income	*	$10,654,802
Special Benefits for Disabled Coal Miners	*	$948,248
Limitation on Administrative Expenses	$4,159,496	$4,097,900

* SSA's budget request to the Department focused only on discretionary programs--i.e., the energy program and administrative costs--which is why appropriation estimates were not provided for the entitlement program accounts at that time.

SERVICE TO THE PUBLIC

Question. In fiscal year 1987, it appears you will be serving a million more people than you did in fiscal year 1986--in terms of cash benefits under the old age and survivors insurance, disability insurance, and supplemental security income programs. How many more beneficiaries do you expect to be serving by 1990, with 25 percent fewer staff?

Answer: By 1990 the number of beneficiaries receiving OASDI benefits, SSI benefits, or both will have grown by 2 million, a 5 percent increase over the 1987 level. Achievement of our original target of reducing 17,006 FTE's over a 6-year period would represent a 21 percent decrease between fiscal years 1984 and 1990.

Question. I have a letter from Social Security Management Associations pointing out some of the less favorable results of the

GAO survey on Social Security services: 25 percent of clients reached Social Security offices only after 3 or more calls; one-third of clients visiting local offices had to wait 30 minutes or more to be served; and, 30 percent of SSI recipients rated services fair to poor. Are you satisfied with this level of service? What are your standards for an acceptable level of quality of service?

Answer. Because of the size of SSA, its importance to the country, and the number of people we serve, we can be both proud of our accomplishments and, at the same time, dissatisfied that there are those who feel that they weren't served well enough.

Overall, I would say that we are pleased with the results of the January 1986 GAO survey entitled "Quality of Services Generally Rated High by Clients Sampled." The survey revealed that the vast majority of the people we serve felt that the quality of the service we provided was good and that our employees were courteous. It is our view that an overall finding of 7 percent who described the service they received as "poor" to "very poor" in a small sample which included people who had been denied entitlement under one of the programs we administer is not cause for alarm. This is not to say, however, that we will be satisfied with the service we provide as long as there is some number of dissatisfied people with whom we have had contact. Our goal is and always has been to provide the best possible service to the public.

The same reasoning may apply to those who indicated they had to wait 30 minutes or more to be served. Our own records indicate an average waiting time of about 12 minutes nationally, with 75 percent of all office visitors referred to an interviewer in 15 minutes or less.

The survey also showed that about 47 percent of the people trying to reach us by telephone were able to get through on the first try, 28 percent on the second try, and that 25 percent of the callers had to call 3 or more times. We are not satisfied with that kind of call completion record if, in fact, it is truly representative of the quality of the telephone service we provide over an extended period of time. We should point out that the volume of calls we receive from the public has its peaks and valleys; for example, calls increase dramatically during the first week of the month when benefit checks are mailed out. It would not, of course, be efficient to have either the staff or the telephone line resources in place during an entire month just to meet the needs of that 1 week "peak" situation. Therefore, if, as I suspect, a significant percentage of survey respondents were basing their experience on "check week" calls, our record does not look quite as bad. Perhaps we need to look into ways of being more effective in our efforts to encourage the public to call during less busy periods.

As you know, we do not have nationally established standards for service or production rates. Nevertheless, our goal is to continually strive to improve all aspects of our service to the public.

Question. Your budget justification refers to a GAO report, issued in January 1986, as corroborating evidence that good service

to the public is being provided, despite staff cuts. Isn't it true that the GAO survey was based on client contacts with Social Security offices in September 1984, before you began the 5 year plan to cut 17,000 staff? Why not use the GAO report as a baseline to periodically measure any change in client attitudes?

Answer. Yes, the GAO survey was conducted in 1984, before the beginning of the 6-year period FY 1985-1990, during which our goal is to achieve employment reductions of approximately 20 percent. However, it is important to note that SSA already was reducing employment during FY 1984.

In its comments on GAO's report, HHS agreed that periodic surveys of client perceptions of the quality of SSA service should be conducted and the results reported to Congress. Currently, SSA is exploring various approaches to conducting the ongoing client surveys which GAO recommended.

AFDC FISCAL SANCTIONS

Question. Your fiscal year 1987 budget assumes you will collect $777 million from sanctions imposed on the States due to error rates under the AFDC program. Yet the House and Senate appear near agreement on reconciliation legislation that would impose a 2 year moratorium on AFDC sanctions. What modifications can you suggest to make error rate sanctions less of a punitive budget-cutting tool and more of a management improvement device?

Answer. The Consolidated Omnibus Budget Reconciliation Act (COBRA), enacted into law on April 7, 1986, provides for a 2-year moratorium on the collection of AFDC QC disallowances. Therefore, we cannot proceed with the disallowance collection activity anticipated in the FY 1987 budget.

We do not view Quality Control disallowances to be either a "sanction" or a "punitive budgeting-cutting tool." Rather, the so-called "sanctions" are disallowances of excess erroneous payments which are made by the States and which exceed the limits specifically set in the statute. We would further note that one of the most significant management improvements in the AFDC program has been the dramatic drop in the payment error rate from 16.5 percent to 6 percent from 1973 to 1984. While the 6 percent payment error rate represents a marked improvement, it means that over $800 million in Federal and State tax dollars were misspent in the AFDC program in fiscal year 1984. This error reduction was directly attributable to the Federal emphasis, through its quality control disallowance policy, on fiscal accountability.

VOCATIONAL REHABILITATION

Question. You are projecting that 4 million beneficiaries will be paid in excess of $20 billion under the disability insurance program in fiscal 1987. What efforts are being made to help people who want to work get training and find jobs?

Answer. The Social Security Administration takes an active role in helping people who want to return to work. All applicants for disability benefits/payments are screened by the State disability determination services (DDS') for vocational

rehabilitation potential. Those determined to have such potential are referred to the State vocational rehabilitation agency (VRA) for services designed to return them to work. The VRA is responsible for developing a rehabilitation program for the individual and carrying out such a program. If successful, the State VRA submits a claim to SSA for reimbursement of the costs of the services.

The Social Security disability program also contains a number of incentives to permit individuals to attempt to return to work without automatic and immediate cut-off of benefits. These incentives include a trial work period for up to 9 months, an extended period of eligibility, and extension of Medicare coverage. SSA's numerous district offices play an active role in informing claimants and beneficiaries of these incentives.

SSA is actively exploring alternatives to current work incentives and rehabilitation methods. With the recent passage of the Consolidated Omnibus Budget Reconciliation Act of 1985, SSA's authority to conduct demonstrations of new approaches for assisting the disabled to return to work has been renewed. Using this authority SSA plans a comprehensive series of projects to test successful return to work under various configurations of services and benefits which bridge the gap between benefit status and work status. Preliminary efforts, which did not require the new legislation, were begun in the current fiscal year. SSA has funded 10 vocational rehabilitation projects operated by the State VRA's and 19 employer-based projects directed by private rehabilitation agencies, universities, business organizations, and labor unions.

Question. To what extent do staff of local Social Security offices work with other agencies to help disabled people get off the benefit rolls and into permanent jobs?

Answer. Local Social Security offices work with other agencies in a variety of ways to help the disabled obtain employment. Each local Social Security office provides all disability applicants with information not only about benefits but also about rehabilitation services which may be available. Once the individual has been referred and accepted for such services by a VRA, staff of the local Social Security office work with that agency in helping assure that the individual cooperates with the rehabilitation agency, in providing whatever information may be needed by such agency, and in giving any other assistance which the VRA may need in providing services to the applicant for SSA benefits.

In addition, the disability program contains a number of work incentives which are discussed with claimants and beneficiaries when they call or visit the office and the provisions appear to be relevant to the individual's situation. These provisions allow for return to work without automatic and complete cut-off of benefits. Under these provisions, individuals attempting to return to work may do so using the protection of the trial work period, the extended period of eligibility, and extension of Medicare coverage. There are special work incentive provisions for SSI disabled recipients (Section 1619 a and b) which are also discussed by staff in the local offices.

Finally, the local office maintains a list of local agencies and organizations that assist the aged, disabled and needy. In

cases where these kinds of contacts appear to be needed to supply additional benefit or service, the individual is provided information and assistance in making such a contact.

Question. What special projects have you initiated to help the disabled obtain suitable employment?

Answer. The local Social Security office maintains a list of local agencies and organizations that assist the aged, disabled and needy. In cases where these kinds of contacts appear to be needed to supply some additional benefit or service, the individual is provided information and assistance in such a contact. Also, as I have indicated, SSA has funded 10 vocational rehabilitation projects operated by the State VRA's and 19 employer-based projects directed by private rehabilitation agencies, universities, business organizations, and labor unions.

PLANS FOR CONTINUING DISABILITY REVIEWS

Question. Your budget indicates that continuing disability reviews would be resumed in January 1986. What is the current status of continuing disability reviews, and what is planned for fiscal 1987?

Answer. For the period January through March 1986, approximately 63,500 continuing disability reviews (CDR's) were released to the district offices and Disability State Agencies. Contacts with these beneficiaries are currently being made to determine if any medical improvement has occurred. The total number of CDR's that we will be able to process in FY 1986 is currently estimated at 170,000. This level takes into consideration our concern for accurate application of the new standards and our priority to process the mental impairment cases already in the pipeline. The FY 1987 budget request assumes processing 478,200 CDR's.

Question. How much more is included in the budget to process continuing disability reviews?

Answer. The budget includes $226.2 million in FY 1987 for processing continuing disability reviews (CDR's). This amount includes resources for processing CDR's in SSA's central office and district offices as well as in the Disability State Agencies.

Question. Does the fact that continuing disability reviews have not been conducted during the past few years account for the recent increase in the size of the disability rolls?

Answer. The number of disabled worker beneficiaries increased from an 8 year low in 1983 by 3.4 percent through 1985, a relatively small increase. A number of factors are involved in this increase, including growth in the number of applicants, allowance rate changes, the aging of the disabled worker population, as well as the absence of continuing disability reviews. It is not possible to identify precisely the effect of any one of these factors.

Question. Have all the rereviews of people with mental impairments been conducted and, if so, what was your experience?

Answer. As indicated in our budget justification, SSA estimates that there are approximately 185,000 mental impairment cases to rereview. Of these, approximately 17,000 cases have undergone the rereview. Individual State plans have been formulated for processing the remaining cases as quickly as possible. The budget projects that the rereviews will be done by September 30, 1986. It's too early to report on the outcome of the mental impairment rereviews since our experience and management information to date is very limited.

HOUSEHOLDS SERVED BY ENERGY PROGRAM

Question. Oil prices have been falling, and States are about to get extra funds for energy programs from the court-ordered release of Exxon oil overcharge funds. How many low-income households do you expect to be helped next winter with heating assistance as a result of lower energy prices and the availability of oil overcharge funds?

Answer. Exxon funds have been distributed to the State Governors who have the flexibility of using the funds under one or more of five energy programs designated in Section 155 of P.L. 97-377. One of these programs is LIHEAP. Currently, we do not have information available as to how the Governors plan to allocate these funds among the five programs.

While oil prices have dropped, it is uncertain whether this trend will continue. Further, States under the LIHEAP block grant have discretion in setting eligibility and benefit levels. As a result, we cannot estimate the number of low-income households who will be helped next winter with heating assistance.

Question. How much progress are we making in narrowing the gap between the number eligible for assistance and those actually getting help under the low income home energy assistance program?

Answer. The following table provides the requested information for fiscal years 1982 through 1985. We do not have data available for fiscal year 1986.

Households	Federal Fiscal Year 1982	1983	1984	1985
LIHEAP Households 1/	6.3	6.8	6.8	6.9
Eligible Households 2/	22.0	22.2	23.4	22.8
LIHEAP Households as a % of Eligible Households 3/	28%	31%	29%	30%

1/ Households assisted with heating costs through LIHEAP heating/crisis assistance, numbers expressed in millions.

2/ Households eligible under the Federal maximum income standard, numbers expressed in millions.
NOTE: States may establish more stringent eligibility requirements than those set forth in Federal statute.

3/ Households served through LIHEAP shown as a percent of households eligible under the Federal maximum income standard.

STATE USE OF ENERGY OVERCHARGE FUNDS

Question. As the result of a recent court decision, the Department of Energy has distributed $2.1 billion to the States, which can be used for five energy programs, including assistance to low-income people in paying fuel bills. How much of this money do you expect States to spend to supplement the low-income home energy assistance program? What efforts will you make to assure that these funds are used to supplement, not supplant, low-income home energy appropriations, as intended by law?

Answer. The court in U.S. vs. Exxon directed the Department of Energy (DOE) to distribute over $2 billion in settlement funds to the States to be used consistent with the requirements of P.L. 97-377 (Warner Amendment). States are not required to report on the use of Exxon settlement funds to HHS. However, P.L. 97-377 requires States to report within 1 year to DOE on the use of the funds, and the court's order requires States to report annually to the court.

While we do not know how much of these settlement funds will be used for LIHEAP, we do know that States so far have used about $43 million out of the $200 million previously distributed under P.L. 97-377 (Warner Amendment) for LIHEAP, which equals approximately 20 percent. Although the Exxon settlement funds may be used for the same programs as the Warner Amendment funds, we do not know whether the use States made of the $200 million of Warner Amendment funds serves as a useful guide as to how States will use Exxon funds. We hope to have more information on States' use of Exxon funds after completion of a telephone survey this summer.

Pursuant to the court's order incorporating the provisions of P.L. 97-377, Exxon settlement funds must be used to supplement, not supplant, funds otherwise available for the designated program. The court and DOE, rather than HHS, have primary responsibility for the enforcement of this provision. By incorporating P.L. 97-377 in its order, the court provided the Exxon settlement funds used under LIHEAP (or the four DOE programs) should be treated as if appropriated for those programs. Under our statutory oversight responsibilities for LIHEAP, we monitor State LIHEAP programs in a variety of ways. If States choose to use Exxon funds in their LIHEAP programs, we will continue to monitor their programs in the same way. Where we discover that Exxon settlement funds have supplanted LIHEAP funds or have been used inconsistently with LIHEAP provisions, we will report such finding to DOE and the court.

Question. Will the Office of Family Assistance or the Department of Energy monitor how the States spend the money--particularly to make sure it is not diverted for such nonenergy purposes as road construction?

Answer. The court and DOE have primary responsibility for oversight of the Exxon settlement funds. We do not have information at this time on DOE's plans to monitor States' disposition of Exxon funds. However, OFA will use the same measures of accountability for the Exxon funds used for LIHEAP as for appropriated LIHEAP funds in determining whether such funds are used consistent with the LIHEAP statute. Where we discover that Exxon funds are used in a

manner inconsistent with the LIHEAP statute, we will report our findings to the court and to DOE.

USE OF PSYCHIATRISTS IN MENTAL IMPAIRMENT CASES

Question. I understand that the review of mental impairment cases is taking considerably more time with psychiatrists. Are you having any problem getting enough psychiatrists to keep up with the workload?

Answer. Public Law 98-460 requires that SSA make every reasonable effort to have a qualified psychiatrist or psychologist review a mental impairment claim before any unfavorable decision is made. The Administration has a goal that would ensure that favorable decisions also receive specialty review. SSA has made considerable progress in hiring these specialists. Of particular value is the involvement of the American Psychiatric Association and the American Psychological Association (APA's). These organizations have alerted their memberships through their newsletters of SSA's needs in this area. The APA's and the Mental Health Liaison Group are continuing to work with our regional offices and States to ensure that sufficient numbers of psychiatrists and psychologists are obtained. Since the law was enacted on October 9, 1984, the number of qualified specialist (psychiatrists/psychologist) workyears in the States has gone up from 120 to 248, or an increase of over 107 percent. This number of staff is sufficient to obtain the allotted statutorily required specialist reviews in unfavorable decisions involving a mental impairment, and to make major progress in reviewing favorable decisions as well.

Question. Are you able to pay psychiatrists sufficient amounts to attract them into the program?

Answer. The States hire psychiatrists and psychologists at their own payment rates, and these rates have been sufficient within the States to obtain the number of staff needed.

SLIPPAGE IN CLIAMS MODERNIZATION PROJECT

Question. The General Accounting Office has indicated your claims modernization project--expected to produce nearly a third of the 17,000 staff reduction over 5 years--has slipped by about 1 year. Is the claims modernization project indeed behind schedule, and if so, why?

Answer. The claims modernization project has slipped behind the schedule originally envisioned for two reasons. First, the Data Communications Utility Project, on which claims modernization depends, has been held up by procurement delays and vendor protests. Second, we have found it necessary to factor in a learning curve, not previously included, for those who will be trained to use the new system.

Question. If implementation of your systems modernization plan is delayed, won't you need to maintain a larger staff in the interim?

Answer. SSA took into account the slippage in the claims modernization project (CMP) in developing our fiscal year 1987

budget, which reflects only a modest reduction due to implementation of the CMP. We will continue to make appropriate adjustments year-to-year, but we are convinced that the long term estimates of FTE savings are in the ballpark. Experience in our York, Pennsylvania and Baltimore, Maryland pilot offices confirms this.

ISSUANCE OF ENERGY REGULATIONS

Question. In a response for last year's hearing record, you indicated regulations were being developed to help prevent waste, fraud, and abuse in the low-income home energy assistance program (p. 1167). This year's budget justification indicates such regulations have not yet been issued. What is your target date for issuing these regulations?

Answer. We expect to issue regulations by the end of April 1986.

Question. Why is it taking so long to get regulations out?

Answer. Regulatory issues concerning implementation of the Human Service Reauthorization Act are complex. For example, for many of the issues the Department has strived to maintain a balance between uniform Federal rules while maintaining State flexibility, which has historically been provided under the block grant. As a result, the regulations have taken longer to issue than we would have liked. However, in the absence of these regulations the statute has been in effect. We expect the regulations to be issued shortly. They will reflect Congressional intent in that States remain the primary interpreters of the statute.

AUDITS OF STATE ENERGY ASSISTANCE PROGRAMS

Question. How many States have audited their low-income home energy assistance programs, and what have these audits and your compliance reviews revealed?

Answer. We have received audits from 39 States for FY 1982, 36 States for FY 1983, 15 States for FY 1984 and 1 State for FY 1985. The LIHEAP statute does not specify when audits must be completed but requires that they be submitted to the Secretary within 30 days of completion. No major compliance issues have been discovered in the audit process.

We conduct onsite reviews of 10 to 12 LIHEAP programs each fiscal year. Thus far, no review has indicated that the grantee was failing to use its LIHEAP funds substantially in compliance with the statute. The results of audit and compliance reviews indicate that the block grant is working well and that existing enforcement mechanisms are adequate to deal with these issues.

ADJUSTMENTS TO AFDC BUDGET REQUEST

Question. Your budget assumes legislative savings of $421 million in the AFDC program. Together with the assumption that error rate sanctions will save $777 million, it appears your assistance payments budget would be understated by $1.2 billion.

Can you give us an updated, more realistic assessment of the fiscal 1987 assistance payments budget?

Answer. The "Consolidated Omnibus Budget Reconciliation Act" recently enacted into law, contains a provision which provides for a 2 year moratorium on the collection of AFDC disallowances while the Department and the National Academy of Sciences each conduct a study of the quality control system. This law will prevent us from collecting any disallowances in FY 1987. Therefore, we will not have the $777.2 million savings for FY 1987 projected in the budget for disallowances. We are committed to realizing the budget savings from our legislative proposals. Other than the change for disallowances, at this time we do not have any revised estimates for the FY 1987 assistance payments budget.

STATUS OF AFDC LEGISLATIVE PROPOSALS

Question. What is the status of your proposed AFDC legislative changes?

Answer. Four of the proposed legislative changes are included in S.1081 which was introduced in the Senate on May 7, 1985 and H.R. 2944 which was introduced in the House on July 10, 1985. These changes would: require all employable individuals to participate in a work activity; remove the employable parent or caretaker relative from the assistance unit when the youngest dependent child becomes 16; define what individuals may be considered essential persons; and prohibit assistance to minor parents who do not live with their own parents, except under limited circumstances.

Two additional proposed legislative changes are included in a draft bill, the Family Assistance and Child Support Enforcement Administrative Improvement Act. The draft bill was sent by the Secretary of Health and Human Services to the Congress on March 31, 1986. These changes modify the administrative costs proposal that is also included in both S.1081 and H.R. 2944 by phasing-down enhanced Federal matching for mechanized claims processing and information retrieval systems and reducing the 50 percent matching rate for AFDC administrative costs for so much of a State's expenditures that exceed 175 percent of the national median. The proposals also modify S.1081 and H.R. 2944 by providing an open-ended 50 percent Federal match for administrative costs related to implementation of work programs.

PROCESSING CONTINUING DISABILITY REVIEWS

Question. What volume of workload do you expect the States to be facing in fiscal 1987 from disability reviews?

Answer. The FY 1987 budget includes plans for the States to process 478,200 continuing disability reviews.

Question. Do you expect delays to develop in the timely processing of benefits?

Answer. We do not expect any delays in timely service to the public.

Question. Will the States have total discretion in how they process workloads, or will the Social Security Administration prescribe timetables?

Answer. SSA has worked and will continue to work closely with each State to develop workload processing plans individually tailored to the unique circumstances and capacities of the State. This is a cooperative effort in which priorities and timetables are mutually agreed to, and SSA does not anticipate any significant problems to arise in developing these processing plans.

SURPLUS FUNDS IN THE SOCIAL SECURITY TRUST FUNDS

Question. Is it true that the Social Security system is expected to generate enormous surplus funds in the near future?

Answer. Under the current Social Security financing schedule, substantial trust fund assets are projected to accumulate during the remainder of this century and the early part of the 21st century, reaching about five times the annual cost of the program. This estimate is based on the intermediate (II-B) assumptions in the current Trustees Report.

Question. Does this mean that the Social Security tax will be higher than necessary?

Answer. After the trust funds accumulate in the early part of the 21st century the surplus will be needed to cover increased benefit payments as the "baby boom" generation retires. At that time, accumulated trust fund assets will begin to be drawn down to meet program costs not covered by concurrent income. Overall, throughout the 75-year valuation period under the Intermediate (II-B) assumptions in the 1986 Trustees Report the average income rate is about 97 percent of the average cost rate, placing the system in close actuarial balance. If the Social Security payroll taxes scheduled for the remainder of this century and the early 21st century were to be reduced, then taxes to be paid later on would have to be increased or benefits reduced to maintain the close actuarial balance of the system.

Question. What becomes of these surplus funds?

Answer. Generally, the law requires that all trust fund assets not needed for current expenses be invested only in U.S. Government securities bearing rates of interest similar to those for long-term securities issued to the general public.

SUPPLEMENTAL APPROPRIATION FOR PAYMENTS TO TRUST FUNDS

Question. In fiscal 1985, Congress appropriated a $3.5 billion supplemental for payments to Social Security trust funds. How much of this supplemental was actually used?

Answer. SSA's actuaries completed their determination in November 1985. The determination provided for a transfer of $3,220 million from the general fund of the Treasury to the OASDI trust funds. These amounts were transferred to the trust funds on December 30, 1985. This payment is an adjustment made every 5 years

to ensure that the trust funds receive an amount equal to the present value of claims arising from gratuitous wage credits granted for pre-1957 military service.

STATE ALLOCATIONS UNDER ENERGY ASSISTANCE PROGRAM

Question. Provide for the record a State-by-State allocation, assuming fiscal 1987 LIHEAP appropriation levels of $1.2 billion, $1.6 billion, $1.9 billion, $2.1 billion and $2.3 billion.

Answer. Under the formula included in the Human Services Reauthorization Act (HSRA), LIHEAP allocations are based on each State's share of national expenditures by low-income households for heating and cooling. The HSRA requires HHS to use the most recent satisfactory available data in calculating State allotments. Following is a State-by-State list of estimated allocations with appropriations levels of $1.2 billion, $1.6 billion, $1.9 billion, $2.1 billion and $2.3 billion assuming $2.358 million for Federal administration. Two things should be noted. First, these estimates are based on data reflecting heating and cooling costs of low-income households which were available for calculating FY 1986 allocations and may change as new data become available for calculating FY 1987 allocations. Second, where the appropriation level drops below $1.975 billion, State allocations are based upon the percent of funds the States received prior to the passage of the HSRA, i.e., their FY 1984 percentages.

State	Estimated FY1987 Allotments $1.2B/$2.358M	Estimated FY1987 Allotments $1.6B/$2.358M
Alabama	$10,286,310	$13,721,831
Alaska	$6,565,982	$8,758,952
Arizona	$4,974,581	$6,636,040
Arkansas	$7,848,940	$10,470,405
California	$55,183,061	$73,613,631
Colorado	$19,240,613	$25,666,778
Connecticut	$25,100,059	$33,483,218
Delaware	$3,331,549	$4,444,252
DC	$3,898,080	$5,199,998
Florida	$16,276,014	$21,712,034
Georgia	$12,868,684	$17,166,692
Hawaii	$1,295,947	$1,728,780
Idaho	$7,505,122	$10,011,753
Illinois	$69,472,631	$92,675,768
Indiana	$31,455,256	$41,960,984
Iowa	$22,292,761	$29,738,311
Kansas	$10,237,836	$13,657,167
Kentucky	$16,369,209	$21,836,355
Louisiana	$10,516,174	$14,028,467
Maine	$16,260,838	$21,691,789
Maryland	$19,218,798	$25,637,678
Massachusetts	$50,208,432	$66,977,527
Michigan	$65,958,174	$87,987,520
Minnesota	$47,519,133	$63,390,030
Mississippi	$8,818,914	$11,764,339

State	Estimated FY1987 Allotments $1.2B/$2.358M	Estimated FY1987 Allotments $1.6B/$2.358M
Missouri	$27,750,081	$37,018,320
Montana	$8,803,031	$11,743,151
Nebraska	$11,024,626	$14,706,736
Nevada	$2,336,413	$3,116,751
New Hampshire	$9,503,432	$12,677,479
New Jersey	$46,610,720	$62,178,216
New Mexico	$6,227,832	$8,307,863
New York	$152,191,065	$203,021,301
North Carolina	$22,681,085	$30,256,332
North Dakota	$9,562,754	$12,756,615
Ohio	$61,458,926	$81,985,569
Oklahoma	$9,455,232	$12,613,182
Oregon	$14,912,289	$19,892,839
Pennsylvania	$81,749,047	$109,052,381
Rhode Island	$8,264,594	$11,024,883
South Carolina	$8,169,427	$10,897,931
South Dakota	$7,766,631	$10,360,606
Tennessee	$16,581,658	$22,119,760
Texas	$27,077,858	$36,121,582
Utah	$8,941,159	$11,927,413
Vermont	$7,123,161	$9,502,222
Virginia	$23,410,645	$31,229,558
Washington	$24,528,661	$32,720,979
West Virginia	$10,832,748	$14,450,774
Wisconsin	$42,774,043	$57,060,129
Wyoming	$3,579,844	$4,775,474
	$1,196,020,057	$1,595,478,345
Appropriation	$1,200,000,000	$1,600,000,000
Adm	$2,358,000	$2,358,000
Difference	$1,197,642,000	$1,597,642,000
Territories	$1,621,943	$2,163,655
States	$1,196,020,057	$1,595,478,345

State	Estimated FY1987 Allotments $1.9B/$2.358M	Estimated FY1987 Allotments $2.1B/$2.358M	Estimated FY1987 Allotments $2.3B/$2.358M
Alabama	$16,298,472	$20,051,406	$27,829,023
Alaska	$10,403,679	$10,815,202	$10,815,201
Arizona	$7,882,134	$9,697,099	$13,458,447
Arkansas	$12,436,504	$15,300,170	$21,234,862
California	$87,436,558	$107,569,951	$130,137,690
Colorado	$30,486,402	$31,692,305	$31,692,305
Connecticut	$39,770,588	$41,343,730	$41,343,730
Delaware	$5,278,779	$5,988,415	$6,559,382
DC	$6,176,437	$6,725,353	$7,366,583
Florida	$25,789,049	$31,727,311	$44,033,827
Georgia	$20,390,197	$25,085,304	$34,815,491
Hawaii	$2,053,404	$2,134,629	$2,134,629
Idaho	$11,891,728	$12,362,111	$12,362,111
Illinois	$110,078,121	$121,413,574	$132,989,770
Indiana	$49,840,281	$54,542,614	$59,742,988

State	Estimated FY1987 Allotments $1.9B/$2.358M	Estimated FY1987 Allotments $2.1B/$2.358M	Estimated FY1987 Allotments $2.3B/$2.358M
Iowa	$35,322,475	$36,719,670	$36,719,670
Kansas	$16,221,664	$18,058,954	$19,780,788
Kentucky	$25,936,713	$30,884,271	$33,828,937
Louisiana	$16,662,685	$20,499,485	$28,450,907
Maine	$25,765,002	$26,784,147	$26,784,147
Maryland	$30,451,837	$37,463,764	$44,073,162
Massachusetts	$79,554,348	$82,701,153	$82,701,153
Michigan	$104,509,529	$114,991,420	$125,955,294
Minnesota	$75,293,203	$78,271,456	$78,271,456
Mississippi	$13,973,409	$17,190,966	$23,859,066
Missouri	$43,969,500	$50,084,219	$54,859,506
Montana	$13,948,242	$14,499,970	$14,499,970
Nebraska	$17,468,319	$18,159,286	$18,159,286
Nevada	$3,702,004	$4,554,438	$6,321,032
New Hampshire	$15,058,015	$15,653,641	$15,653,641
New Jersey	$73,853,839	$86,621,163	$94,880,071
New Mexico	$9,867,887	$11,919,535	$13,056,005
New York	$241,143,978	$250,682,526	$250,682,526
North Carolina	$35,937,768	$44,212,901	$55,191,480
North Dakota	$15,152,011	$15,751,355	$15,751,355
Ohio	$97,380,552	$113,918,675	$124,780,269
Oklahoma	$14,981,644	$18,431,359	$25,580,588
Oregon	$23,628,251	$24,562,876	$24,562,876
Pennsylvania	$129,529,881	$134,653,488	$134,653,488
Rhode Island	$13,095,100	$13,613,082	$13,613,082
South Carolina	$12,944,309	$15,924,902	$22,101,916
South Dakota	$12,306,086	$12,792,859	$12,792,859
Tennessee	$26,273,336	$32,323,109	$37,786,910
Texas	$42,904,375	$52,783,659	$73,257,595
Utah	$14,167,104	$14,727,489	$14,727,489
Vermont	$11,286,519	$11,732,961	$11,732,961
Virginia	$37,093,743	$41,692,411	$45,667,580
Washington	$38,865,218	$40,402,548	$40,402,548
West Virginia	$17,164,293	$18,736,181	$20,522,585
Wisconsin	$67,774,694	$70,455,549	$70,455,549
Wyoming	$5,672,197	$5,896,563	$5,896,563
	$1,895,072,061	$2,094,801,205	$2,294,530,349
Appropriation	$1,900,000,000	$2,100,000,000	$2,300,000,000
Adm	$2,358,000	$2,358,000	$2,358,000
Difference	$1,897,642,000	$2,097,642,000	$2,297,642,000
Territories	$2,569,939	$2,840,795	$3,111,651
States	$1,895,072,061	$2,094,801,205	$2,294,530,349

DISTRIBUTION OF ENERGY OVERCHARGE FUNDS

Question. Also provide for the record a State-by-State distribution of the $2.1 billion available from the Exxon oil overcharge case.

Answer. The table that follows shows the State-by-State distribution of the $2.1 billion available from the Exxon oil overcharge case.

State	Exxon Overcharge Amount
Alabama	$ 32,192,086.26
Alaska	8,272,460.20
American Samoa	371,275.67
Arizona	21,565,619.62
Arkansas	25,949,670.45
California	194,717,034.50

State	Exxon Overcharge Amount
Colorado	22,715,884.22
Connecticut	34,900,268.97
Delaware	9,944,769.60
Dist. of Col.	4,603,515.75
Florida	98,114,523.64
Georgia	46,625,490.97
Guam	3,099,681.29
Hawaii	14,482,089.88
Idaho	8,690,739.43
Illinois	96,105,505.93
Indiana	51,631,387.53
Iowa	27,423,669.23
Kansas	23,958,453.17
Kentucky	27,438,633.15
Louisiana	51,536,267.21
Maine	15,094,373.28
Maryland	36,415,978.69
Massachusetts	70,340,939.14
Michigan	70,991,489.94
Minnesota	36,066,224.67
Mississippi	28,378,643.38
Missouri	41,516,281.45
Montana	9,584,665.67
Nebraska	15,504,944.23
Nevada	8,767,274.85
New Hampshire	9,797,536.77
New Jersey	75,432,931.59
New Mexico	13,692,730.49
New York	159,874,589.05
No. Mariana Islands	192,061.70
North Carolina	47,029,796.82
North Dakota	7,721,443.24
Ohio	79,740,285.12
Oklahoma	26,234,258.14
Oregon	20,721,692.22
Pennsylvania	96,803,642.42
Puerto Rico	20,053,948.64
Rhode Island	8,005,286.31
South Carolina	25,187,596.62
South Dakota	7,501,993.25
Tennessee	34,603,233.87
Texas	157,187,086.87
Utah	12,454,477.95
Vermont	5,005,193.65
Virgin Islands	9,951,205.30
Virginia	53,376,861.04
Washington	32,121,634.15
West Virginia	12,902,924.70
Wisconsin	36,966,568.55
Wyoming	8,874,385.60

Question. In 1982 SSA began a massive 5 year modernization of ITS systems at an estimated cost of $500 million. Last year the estimated cost had risen to $863 million and the completion date was moved back to 1989. Have the estimated cost and completion date of the systems modernization plan changed again?

Answer. The original Systems Modernization Plan (SMP) was published in March 1982 and was designed to cover the initial 5-year period from March 1982 through February 1987. However, in presenting the original plan SSA advised Congress that each year would be the first year of a new 5 year plan. This approach enables SSA to pursue state-of-the-art technology and systems capability. As a result, last year's plan reflected the SMP costs and projects for the period March 1982 through FY 1989, a 7 1/2 year modernization effort. The 1986 SMP, which was published in October 1985, reflects an estimated cost of $990 million for the 8 1/2-year period of March 1982 through FY 1990. Each new SMP update continues the strategic direction of the original 1982 SMP but adds those initiatives necessary to ensure that SSA continues its modernization efforts. For example, the original SMP did not include the Administrative/Management Information Engineering Program or the System Operations Management Program; both of which are included in the 1986 SMP update. Each annual plan represents an additional year of continuous modernization, not a corresponding delay in the original SMP objectives. For comparison purposes, the original SMP's projected cost was $479 million, while the current estimate for the same period (March 1982 to February 1987) is $493 million.

Question. Please submit for the record a detailed description of the areas of increased cost and slippage of completion dates of all the major components of this project since its inception.

Answer. Since the 1982 SMP was published, SSA has added two major modernization programs that were not included in the original plan:

- o The System Operations Management Program--to modernize operations in the National Computer Center.

- o The Administrative/Management Information Engineering Program--to modernize our management information systems.

These new programs represent an increase to the original SMP of $28 million and $197 million, respectively, or $225 million of the current 8 1/2 year SMP cost estimate of $990 million (March 1982 through September 1990). As I have indicated, by way of comparison, the original SMP projected cost was $479 million for 5 years, while the current projected cost for the same period (through March 1987) is $493 million.

SSA has accomplished the Survival and Transition phases of the original plan and has moved into the state-of-the-art phase. Over the next 5 years, SSA will implement major new software systems, a new nationwide telecommunications network and a modern data base architecture. Currently, two major SMP programs are behind the schedule in the original 1982 plan:

- The Data Communications Utility (the new nationwide telecommunications network) is approximately 6 months behind the original schedule because of bidder protests that delayed procurement schedules.

- The Software Engineering Program is about 15 months behind the original schedule. This is due primarily to our underestimation of the magnitude and complexity of this software initiative during the initial 1982 planning process.

SSA is, however, making good progress in terms of our updated project schedules as contained in the 1986 SMP. Our modernized claims process and critical payment systems are now being piloted in SSA's field offices, contracts have been awarded for the functional requirements phases of the redesigned program benefit, data exchange, inquiry/response and quality assurance systems and our redesigned enumeration and National Debt Management systems are in the development stages.

CONTINGFNCY RESERVE AND ITS RELATIONSHIP TO GRAMM-RUDMAN

Question. How much of the FY 1986 contingency reserve for salaries and expenses, which is unusually large in comparison to past years, will not be used, and why?

Answer. We are unable to answer your question, because we do not know in advance what contingency needs will develop. By definition, the contingency reserve is available to meet unanticipated costs. Specifically the appropriation language for the Limitation account permits tapping the reserve for unanticipated costs related to workloads, automation projects and their impact on the workforce, and the Disability State Agencies.

Question. Does providing budget authority for a contingency reserve add to the amount of reductions that must be made in other programs to comply with Gramm-Rudman?

Answer. Providing budget authority for the contingency reserve in SSA's limitation account will not affect budgeted income or outgo, and therefore will have no impact on the amount of reductions that must be made in other programs to comply with Gramm-Rudman.

SOCIAL SECURITY COST-OF-LIVING ADJUSTMENT

Question. How much will next year's (January 1987) cost-of-living adjustment be, and how much will it cost in FY 1987 and the following 4 fiscal years?

Answer. The budget assumes that a 3.7 percent cost-of-living adjustment will be paid in January 1987. However, the actual percentage will be determined by measuring the increase in the consumer price index during the fiscal year ending in September 1986. This index must increase by at least 3 percent before an automatic adjustment will be made.

The projected 3.7 percent increase assumed in the budget for persons receiving OASDI benefits would cost the trust funds $5.5 billion in FY 1987. The cumulative cost for the fiscal years 1988 through 1991 for this increase would be $30 billion.

RESTORATION OF TRUST FUNDS AFTER DEBT CEILING CRISIS

Question. Have the Social Security trust funds been restored to the position they would have been in had the debt ceiling crisis of last fall not emerged, including restoration of lost interest?

Answer. While some decline in the invested assets of the trust funds occurred late in 1985 because of debt limit problems, the assets are now fully invested. Legislative action by Congress, with the support of the Administration, restored the long-term bonds that had been redeemed and prevented any loss of interest earnings to the funds. This legislation also restored interest lost due to similar disinvestment that took place in 1984.

ACHIEVEMENTS IN SERVICE TO THE PUBLIC

Question. In Congressional testimony SSA officials have repeatedly emphasized the Agency's recent efforts to improve quality of service to the public. Would you provide the Committee with a list of the major changes you have made in recent years and how they affect the average claimant or recipient?

Answer. Following is a list of major achievements which have improved SSA's service to its clients.

--Implemented more than a hundred proposals to simplify development and documentation procedures in the claims process. This reduced the "burden of proof" to the public, and allowed SSA to process actions more timely.

--Increased the percentage of cases that are automatically recomputed for additional earnings from 54 to 75 percent. This speeds the process and also ensures greater accuracy.

--Prevented the overpayment of $100 million annually through changes to the annual earnings test process. Working beneficiaries who otherwise might have been overpaid were not.

--Enrolled 1,500 additional employers in our magnetic media wage reporting program. This speeds the posting of wages to wage-earners' records and improves accuracy.

--Automated some SSI actions which had previously accounted for 625,000 manual actions each year. Again, timeliness and accuracy are improved.

--Reduced the time it took to issue new Social Security numbers from 6 weeks to an average of 11 days.

--Since 1982 reduced by 5 days the time taken to process retirement and survivor cases.

--Improved the way service is made available in field offices by offering appointments, service via phone, group interviews in selected circumstances and "speed lines" for business that takes little time. (Expanded claims-taking capability is a continuing emphasis.)

--Improved our written notices so that they are easier to read. This increases our clients' understanding of the notices and decreases their need to call or visit field offices.

STATUS OF PARADYNE CASE

Question. The Paradyne Company, doing multi-million dollar systems work for SSA, has been under investigation for purportedly misrepresenting its products to SSA. What is the status of the Paradyne case? What criminal or civil actions have been taken? What action is still pending?

Answer. In March 1981 SSA entered into a contract with the Paradyne Corporation to provide terminal equipment for SSA offices nationwide. The equipment acquired under the contract has performed satisfactorily. Paradyne was indicted by a Florida grand jury on December 12, 1985. The indictment charges that Paradyne misled SSA during the proposal evaluation phase of the acquisition by a fraudulent demonstration of the equipment. On the basis of the indictment Paradyne was suspended on December 16, 1985 from entering into any new contracts with the Federal Government.

Question. Is the company still doing work for the Agency?

Answer. The terms of the suspension allow the ongoing contract to be renewed if it is determined to be in the Government's best interest. SSA is still renting terminals from Paradyne and plans to renew the contract until a competitive replacement of the equipment is completed.

APPROPRIATIONS LANGUAGE CHANGE FOR TRAVEL REIMBURSEMENT

Question. On the limitation account, you are proposing a language change with respect to travel reimbursements. What is the rationale for this language change?

Answer. This technical language change conforms the language with SSA's longstanding practices regarding the payment of travel expenses in the Supplemental Security Income (SSI) program. It clarifies SSA policy which limits reimbursements to SSI claimants, their representatives and witnesses for travel to hearings on occasions when travel of more than 75 miles is required.

Existing language would apply the 75 miles limitation to travel for consultative (medical) examinations, and it is our belief that Congress did not intend to apply a distance restriction on the payment of travel costs incurred to attend consultative examinations.

RESPONSE TO GAO REPORT ON ADP SYSTEMS' VULNERABILITY TO FRAUD

Question. GAO reported that SSA's systems will remain vulnerable to fraud for up to 7 years while the Agency's systems modernization plan is being implemented. Would you tell us what SSA has done about GAO's report to this committee of last August alleging SSA's automated systems remain vulnerable to fraud because of the Agency's failure to create an adequate system to audit transactions?

Answer. Over the past few years SSA has implemented several measures to improve the security of its current operating system. We recognize that these steps are only interim measures. SSA's objective is to proceed under the Systems Modernization Plan (SMP), with all available resources, to implement a new system containing modern, built-in features that will ensure the safety and security of its operational processes.

To accomplish this objective, SMP design groups have been developing and implementing functional requirements specifications for appropriate internal controls, audit trails, auditability, security and privacy. SSA is now in the first phase of installing its modernized claims system, the design of which includes a new security environment. This system's major security features are: automated security audit trails; personal identification numbers identifying each individual entering or authorizing transaction data; and restricted access to computer and telecommunications resources through use of a commercial software package.

Although a personal identification number procedure is now in use in the current system, SSA has not modified its program software and procedures to require it for all transactions for two reasons. First, to do so would divert a significant amount of resources from SSA's major systems objective--the modernization of outdated computer systems and operational processes under the SMP. Second, the introduction of a personal identification number requirement for all transactions would necessitate changes in operating procedures in SSA field offices at about the same time that the offices will be undergoing conversion and staff training for the new, secure system. Although it is not quantifiable, we believe that this predictable disruption, added to the costs in time and resources, far outweighs the practical advantages that would be gained by the modification.

We believe that by continuing with its SMP automation plans SSA is pursuing the most effective course of action for improving the security and auditability of its systems.

SOCIAL SECURITY OFFICE CLOSINGS

Question. Will Gramm-Rudman result in any office closings?

Answer. No, the Gramm-Rudman-Hollings legislation will not force us to close any field offices.

Question. Please provide the committee with a listing of offices closed in FY 1986 and their approximate size, and a similar listing for FY 1987 and subsequent years.

Answer. The following table displays all the planned field office closings.

Year of Closing	Office	Staff Size	Disposition of Staff
FY 1986	La Grange, IL.	7	All to be reassigned to North Riverside, IL.
FY 1986	Arlington Hts., IL.	15	All to be reassigned to a new larger office to be opened in a central location.
FY 1986	Glenview, IL.	12	
FY 1986	Des Plaines, IL.	18	
FY 1987	Louisville (West), KY.	12	All to be reassigned to Louisville (Downtown) office.

ABSORBING GRAMM-RUDMAN REDUCTIONS

Question. Social Security benefits are exempt from spending reductions required by the Gramm-Rudman-Hollings legislation, but administrative expenses are not. Would you tell the committee how SSA will absorb the $140 million or so in Social Security/SSI administrative spending reductions required this year as a result of Gramm-Rudman?

Answer. The legal requirements for implementing the reductions in FY 1986 necessitated separate reductions totaling $144.3 million in budget resources for three elements in the limitation account (-$6.2 million in the contingency reserve, -$12.3 million in ADP/telecommunications, and -$125.9 in other Federal administrative expenses). Resources budgeted for the State Disability Agencies were not subject to sequestration.

Our current assessment of the impact on SSA in FY 1986 is that SSA can achieve the Gramm-Rudman-Hollings reductions without impairing progress on SSA's systems modernization efforts or resorting to furloughs or reductions-in-force. The $6.2 million reduction in the contingency reserve is not of a sufficient magnitude to threaten program operations or service to the public. We do not expect that the $12.3 million reduction in the ADP/telecommunications budget will impair the progress of systems modernization efforts because funds carried over from FY 1985 should prove adequate. The $125.9 million reduction to the remaining funds in the Limitation on Administrative Expenses account will be taken by reducing personnel services costs--primarily by reducing overtime and nonceiling employment--and costs for other objects of expenditure; for example, travel, training, equipment replacement and supplies.

Question. What is the projected impact next year?

Answer. The 1987 President's budget request for SSA's limitation account does not include a reduction for the Gramm-Rudman-Hollings legislation because the overall Federal budget request submitted by the President in January 1986 is within the governmentwide maximum annual deficit target for FY 1987.

There may be a reduction governmentwide if it is determined in

August 1986 that sequestration of funds is necessary; however, the Gramm-Rudman provision for sequestration will not take effect in FY 1987 unless the Congress and the President fail to agree on a budget that is within the maximum deficit target for 1987. No reasonable prediction can be made at this time.

STATE MECHANISMS FOR PROVIDING ENERGY ASSISTANCE

Question. Provide for the record a State-by-State summary of the mechanisms through which the low-income home energy assistance program is administered, such as direct provision of fuel, vendor lines of credit, direct payments to individuals.

Answer. Following is a table with applicable footnotes from our "Report on the Low Income Home Energy Assistance Program" dated February 28, 1986 which was prepared for the Senate Committee on Appropriations. It provides information on the forms of benefits used by each State for fiscal year 1986.

Table 6-86. LIHEAP heating assistance: Forms of benefits, by state, fiscal year 1986

State	Cash applicants	Payment to categorically eligible households	Vendor payments	2-party checks	Vouchers/ coupons	Payment directly to landlords	Budget payment arranged	Other
Alabama					Yes			
Alaska	Yes	*	Yes	Yes		Yes		Yes
Arizona			Yes			Yes	Yes	
Arkansas	Yes		Yes	Yes			Yes	Yes
California		*		Yes				
Colorado	Yes		Yes	Yes				Yes
Connecticut	Yes*		Yes		Yes		Yes	
Delaware	Yes		Yes					
Dist. of Col.	Yes		Yes					
Florida	Yes							
Georgia	Yes		Yes	Yes				
Hawaii			Yes					
Idaho	Yes			Yes				
Illinois	Yes	Yes	Yes					
Indiana	Yes*		Yes					
Iowa	Yes		Yes	Yes	Yes	Yes	Yes	Yes
Kansas	Yes			Yes				Yes
Kentucky	Yes			Yes				
Louisiana			Yes			Yes		
Maine	Yes		Yes		Yes		Yes	Yes
Maryland	Yes*		Yes			Yes	Yes*	Yes
Massachusetts	*		Yes				Yes	Yes
Michigan	Yes	Yes	Yes	Yes	Yes		Yes	Yes
Minnesota	Yes*		Yes				Yes	
Mississippi	Yes		Yes				Yes	
Missouri	Yes		Yes				Yes	
Montana	Yes		Yes			Yes		Yes
Nebraska	Yes		Yes			Yes		Yes
Nevada	Yes		Yes					Yes
New Hampshire	Yes*		Yes		Yes		Yes	Yes
New Jersey	Yes		Yes	Yes			Yes	Yes
New Mexico					Yes			
New York	Yes		Yes	Yes			Yes	Yes
North Carolina	Yes							
North Dakota	Yes		Yes				Yes	Yes
Ohio	Yes		Yes		Yes		Yes	
Oklahoma	Yes*		Yes				Yes	Yes

Table 6-86. LIHEAP heating assistance: Forms of benefits, by state, fiscal year 1986 (continued)

State	Cash applicants	Payment to categorically eligible households	Vendor payments	2-party checks	Vouchers/ coupons	Payment directly to landlords	Budget payment arranged	Other
Oregon	Yes		Yes				Yes	
Pennsylvania	Yes*	*	Yes					
Rhode Island	Yes		Yes	Yes			Yes	Yes
South Carolina			Yes		Yes	Yes		
South Dakota			Yes			Yes		
Tennessee	Yes			Yes	Yes			
Texas	Yes		Yes				Yes	
Utah	Yes		Yes					
Vermont	Yes*			Yes*				
Virginia	Yes		Yes					
Washington	Yes		Yes				Yes	Yes
West Virginia	Yes		Yes					Yes
Wisconsin	Yes	Yes		Yes			Yes	Yes
Wyoming	Yes					Yes		

STATE-SPECIFIC FOOTNOTES
Table 6-86

Alaska	Payment to categorically eligible households--categorical households are mailed regular applications to complete.
California	Payment to categorically eligible households--recipients of AFDC, SSI, Food Stamps, Veteran and Survivor, and SSP benefits are mailed regular applications.
Connecticut	Cash to applicants--for households with heat in rent.
Indiana	Cash to applicants--to households without a participating vendor or to nonsubsidized renters with heat included in rent.
Maryland	Budget payments arranged--under the winter protection plan.
Massachusetts	Cash to applicants--direct client payment can be made under exceptional circumstances.
Minnesota	Cash to applicants--renters with heating costs included in their rent and self wood cutters may receive direct payments.
New Hampshire	Cash to applicants--only when landlord refuses to accept voucher.
Oklahoma	Cash to applicants--limited to roomer renters.
Pennsylvania	Cash to applicants--heating payments are made directly to applicants only if their rent includes heat or if the vendor refused to participate in the program. Payments to categorically eligible households--categorically eligible households are not required to provide income verification (information contained in existing public assistance records) or to provide information which has not changed from previous years as a result of the mail application process.
Vermont	Two-party checks--some heated rentals and those households that purchase wood get cash, and others receive a two-party check.

Question. Under the low-income home energy assistance programs, States are permitted to provide assistance through a variety of mechanisms. Examples include: direct provision of fuel, payments for energy through vendor lines of credit, and direct financial assistance to individuals. Have you evaluated the cost-

effectiveness of various ways of providing energy assistance to low-income persons?

Answer. Because the block grant concept affords States the flexibility to tailor their LIHEA programs to meet the needs of their low-income households, we feel the States are in the best position to evaluate payment mechanisms in their own programs. Instead, we focus on information exchange activities, such as holding national conferences and funding activities such as the Voluntary Information System for Energy Assistance (VISEA) which provides a forum to focus on different approaches that States are using under the flexibility of the block grant.

We also wish to note that the Human Services Reauthorization Act of 1984 amended P.L. 97-35 to provide for GAO evaluation of State programs not less frequently than every 3 years to assure that expenditures are consistent with the provisions of the law and to determine the effectiveness of the State in accomplishing the purposes of LIHEAP.

RESEARCH AND EVALUATION OF ENERGY PROGRAM

Question. How much is budgeted for research and evaluation of the low-income home energy assistance program?

Answer. A substantial portion of the Federal administrative budget ($2,358,000 requested for FY 1987) is used for research and evaluation. These activities include:

--Data collection and analysis

- o Interagency agreements with the Department of Energy and the Bureau of the Census to gather information on energy usage and cost, demographic characteristics, and housing characteristics of the low-income population.
- o Various research projects that look at State program practices, winter protection rules and utility arrearages/terminations.

--Program reviews to assure compliance with statutory requirements

- o Review of grantee applications.
- o Onsite reviews of grantee programs.
- o Review of grantee audits.

--Information exchange activities designed to facilitate the exchange of information about cost-effective practices among States.

In addition to the Federal administrative activities for research and evaluation, some States have evaluation efforts in place.

RELATIONSHIP OF ENERGY ASSISTANCE AND FOOD STAMPS

Question. Near the end of the last session of Congress, a provision was included in the agriculture authorizing legislation to count low-income home energy assistance payments as income for purposes of determining food stamp eligibility. How many people now

stand to lose their food stamp benefits if they participate in the low-income home energy assistance program?

Answer. In calculating food stamp eligibility and benefits, households are permitted certain deductions from gross income. Under the excess shelter cost deduction, households are allowed to deduct shelter costs in excess of 50 percent of their adjusted income up to a set maximum. Both the House and Senate food stamp amendments contained provisions designed to disallow the deduction of utility costs paid by LIHEAP when calculating the excess shelter cost deductions. However, during floor consideration of P.L. 99-198 (Food Stamp Security Act of 1985) in both the House and Senate, these provisions were struck, leaving the enacted law silent on the deductibility of such costs paid by LIHEAP. Based upon information from the Food and Nutrition Service of the Department of Agriculture, we conclude that the passage of P.L. 99-198 will not adversely affect a household's food stamp benefit based upon the receipt of LIHEAP. P.L. 99-198 does allow (but not require) States to set a separate Standard Utility Allowance for households receiving LIHEAP assistance. We are not aware of any State that has elected to use this authority.

Question. How many others will have their food stamps cut?

Answer. As indicated, provisions originally included in the agriculture authorizing legislation to disallow the deductibility of utility costs paid by LIHEAP were dropped prior to enactment of P.L. 99-198. Based on conversations with Food and Nutrition Services staff, we conclude that P.L. 99-198 should not decrease a household's food stamp benefits based on receipt of LIHEAP.

Question. How much do you estimate low-income people will lose in combined fuel assistance and food stamp benefits as a result of this new authorizing legislation?

Answer. As indicated previously, we do not believe the enactment of P.L. 99-198 will adversely affect a household's food stamp benefits based on the receipt of LIHEAP.

CASH AND MEDICAL ASSISTANCE

Question. The budget proposes to finance refugee cash and medical assistance directly from the Office of Refugee Resettlement (ORR) account and eliminate the source of funding through Aid for Dependent Children (AFDC) and Medicaid. Secondly, the period of funding will be reduced from 36 to 18 months.

Will ORR continue to reimburse States for the cost of General Assistance programs for refugees who qualify under them for the second 18 months after their arrival?

Answer. ORR will not reimburse States for the cost of General Assistance programs for refugees who qualify under them for the second 18 months after their arrival.

Question. What are your plans for assisting refugees who do not categorically qualify for AFDC or Medicaid in months 19-36 after their arrival?

Answer. Under the current program, refugees who do not categorically qualify for AFDC or Medicaid are not covered past the eighteenth month. We have no plans to change that.

Question. How do you propose to change the period of full reimbursement to States from 36 to 18 months?

Answer. The Department is considering how to implement the proposed change to limit Federal payment of the States' share of costs from 31 months to 18 months. A final decision has not been reached.

Question. Can this change be made without the passage of legislation?

Answer. We believe, after consultation with the Department's Office of General Counsel, that the proposed change can be accomplished through the regulatory process.

Question. If required legislation isn't passed, how much more funding will you require to carry out a 36-month program?

Answer. The effect to the Administration's FY 1987 total budget submission would be a net increase of $30,438,000, if ORR were required to carry out a 36-month program.

VOLUNTARY AGENCY PROGRAM

Question. The budget request for FY 1987 is $1 million, a decrease of $2.8 million, or 74 percent. The budget proposes to reduce the Federal matching payment from $957 to $250 per refugee. I understand that this is a very successful program. Refugees are provided with four months of cash and medical assistance and support services in lieu of the standard Office of Refugee Resettlement (ORR) assistance. Furthermore, the dependency rate is extremely low.

My question is, why penalize this program for an effective track record?

Answer. The feeling is that the voluntary agencies participating in this program will continue, through greater private sector support, to serve refugees without the dollar-for-dollar Federal match. It is not viewed as a penalty to the agencies, but an opportunity to serve refugees as they have in the past, prior to generous Federal programs.

Question. Don't you think it is wise to continue funding for a proven alternative program that meets the refugees' special needs and places refugees in jobs?

Answer. We expect that agencies will continue services through private sector support. If this is not the case, there are other opportunities for agencies to provide services under alternative programs, such as under the provisions of the Fish-Wilson announcement.

Question. Given the success of this program, couldn't more refugees participate in this program in its current administrative form (i.e., $1,000 matching grant/refugee)?

Answer. Although some grantees have indicated a desire to serve more refugees, current budget levels and the ability of agencies to raise the necessary amount of match contribution are limiting factors to expanding the program.

REFUGEE ADMISSIONS - CONTINGENCY PLANS

Question. How many new refugees is the Administration budgeting for in FY 1987?

Answer. As indicated on page 17 of the budget justification document, ORR's FY 1987 budget request assumes 68,000 total refugee arrivals in FY 1987. Of that number, 64,000 are budgeted for in the State Administered Program activity, and the remaining 4,000 are covered by the Voluntary Agency Program budget line.

Question. Does ORR have any contingency plans, budgetary or other, regarding the possibility of a sudden large influx of refugees under emergency conditions?

Answer. ORR does not have any contingency plans, budgetary or other, regarding the possibility of a sudden large influx of refugees under emergency conditions.

Question. Would a large influx alter any of your proposals, such as reducing the period of Federal reimbursement to the States?

Answer. No. Lower unemployment rates will continue to ease the resettlement process, and existing established refugee communities will more readily absorb new arrivals. We believe that the shorter period of reimbursement will lead to earlier employment of refugees by encouraging States, voluntary agencies, service providers, and refugees to give greater emphasis to this objective -- the achievement of which we believe is essential to refugees' adaptation and long-term success and well-being in the United States. The present longer period of reimbursement often appears to be an inducement to postponing employment. While it is possible to visualize that a sudden influx under emergency conditions could create various kinds of impacts that would need to be addressed, we would not recommend more than an 18-month period of reimbursement.

WILSON-FISH DEMONSTRATION PROJECTS

Question. Your budget justification (page 20) states that two Wilson-Fish demonstration projects have been awarded grants, one in California and one in Oregon.

Please describe these projects in more detail. How many refugees are involved? What cash assistance barriers to employment are being removed? Is there job placement counseling?

Answer. Please refer to the attached October 31, 1985 Report to Congress for a complete description of the California and Oregon demonstration projects, including a description of the cash assistance barriers to employment that will be removed as a result of the projects. Job placement counseling is an integral part of the Oregon project, and the mandatory referral to employment placement and counseling services, where needed, is a part of the California demonstration.

As of December 31, 1985, there were 8,425 cases involving 37,321 refugees that were being served in the California project. Oregon had about 90 cases involving 170 refugees in its project.

Report to the Congress on Alternative Projects for Refugees Under Section 412(e)(7) of the Immigration and Nationality Act

Introduction

In October 1984, Congress amended the Immigration and Nationality Act to provide authority for the Secretary of Health and Human Services (HHS) to implement demonstration projects for refugees in order to increase their prospects for self-sufficiency, reduce their level of welfare dependence, and promote coordination among the voluntary resettlement agencies and service providers. This provision, generally known as the Wilson/Fish Amendment, was contained in the FY 1985 Resolution on Continuing Appropriations (Pub.L. 98-473).

As part of the amendment, the Secretary is required to report to the Congress not later than October 31, 1985, on the results of these projects and on any recommendations respecting changes in the refugee assistance program to take into account such results. In response to that requirement, this report discusses the development of the program notice to implement the amendment and describes demonstration projects currently in operation in the States of California and Oregon.

The full text of the Wilson/Fish Amendment follows:

> Section 119. (a) Section 412(e) of the Immigration and Nationality Act (8 U.S.C. 1522(e)) is amended by adding at the end thereof the following new paragraph:
>
> "(7)(A) The Secretary shall develop and implement alternative projects for refugees who have been in the United States less than thirty-six months, under which refugees are provided interim support, medical services, support services, and case management, as needed, in a manner that encourages self-sufficiency, reduces welfare dependency, and fosters greater coordination among the resettlement agencies and service providers.
>
> "(B) Refugees covered under such alternative projects shall be precluded from receiving cash or medical assistance under any other paragraph of this subsection or under title XIX or part A of title IV of the Social Security Act.
>
> "(C) The Secretary, in consultation with the United States Coordinator for Refugee Affairs, shall report to Congress not later than October 31, 1985, on the results of these projects and on any recommendations respecting changes in the refugee

assistance program under this section to take into account such results.

"(D) To the extent that the use of such funds is consistent with the purposes of such provisions, funds appropriated under paragraph (1) or (2) of section 414(a) of this Act, part A of title IV of the Social Security Act, or title XIX of such Act, may be used for the purpose of implementing and evaluating alternative projects under this paragraph."

(b) The amendment made by subsection (a) shall take effect on October 1, 1984. (Immigration and Nationality Act, 412(e)(7)(A), 8 U.S.C. 1522(e)(7)(A).)

Development of the Program Notice

To implement the Wilson/Fish Amendment, the Office of Refugee Resettlement (ORR) within HHS developed a draft program notice which was issued for public comment in the Federal Register of February 20, 1985 (50 FR 7132). ORR considered the comments received, modified the notice, and published a final notice on June 11, 1985 (50 FR 24583).

The Office of Refugee Resettlement recognizes that the needs of refugees are often transitional. The public assistance system available to the general population is not necessarily the most responsive mechanism for dealing with the unique needs that refugees have and the obstacles that they must overcome. Therefore the notice invites eligible applicants to submit proposals for alternative approaches which may better promote refugee early employment and self-sufficiency. Proposals can demonstrate alternative approaches to one component of the refugee resettlement system, or to the entire system itself, insofar as those functions are normally funded through the Office of Refugee Resettlement. Because of the difficulty that many refugees have had in moving from receipt of cash assistance to employment and self-support, proposed demonstration projects must serve either welfare-dependent refugees or newly arriving refugees who otherwise could be expected to become welfare-dependent. To be funded, grantees also are required to develop acceptable plans for having their demonstration projects independently evaluated. No additional funds are available for projects approved under the notice. Projects are funded from regular cash assistance, medical assistance, and social service appropriations, as applicable.

Planning for the two projects in California and Oregon began several years before the enactment of the Wilson/Fish Amendment and these projects are currently in operation. Since the publication of the final notice in June, ORR has received and reviewed six other preapplications -- three from voluntary resettlement agencies, two from local entities, and one from a State agency. At this time the Director of ORR has conditionally approved the preapplication from the State of Massachusetts. ORR staff are providing technical assistance to help the applicant develop an acceptable final application. Once the final application is received, it will be evaluated by a panel of refugee program experts, and a funding decision will be made by the Director of ORR. Other preapplications

and applications will continue to be reviewed by ORR during FY 1986 as they are received.

Demonstration Projects in the States of California and Oregon

As we noted before, during the time that the ORR program notice was being developed, California and Oregon were already in the process of developing demonstration projects independently. These projects were approved by ORR in May 1985 under the authority of the Wilson/Fish amendment and both projects were implemented during the summer. Descriptions of the two projects follow.

The California Refugee Demonstration Project (RDP)

Since enactment of the Refugee Act of 1980, the proportion of refugees receiving assistance from the program of Aid to Families with Dependent Children (AFDC), including the AFDC Unemployed Parent (AFDC-UP) program, has increased. At the end of FY 1984, California had an overall cash assistance dependency rate of approximately 85 percent of the State's time-eligible population (refugees who had been in the U.S. less than 36 months). The national average at that time was 54 percent (or 38 percent excluding California). Of the 85 percent of refugees on cash assistance in California, 83 percent were receiving AFDC or AFDC-UP benefits, 12 percent were on refugee cash assistance (RCA), four percent were on SSI, and one percent were on general assistance.

The AFDC program contains certain disincentives to refugee employment. For example, refugee families are usually larger than non-refugee families on public assistance and they often live together in extended family households. The total income from the cash assistance payments, which are based on family size, often exceeds the income that could be earned in entry-level, low-skilled employment. Individuals on AFDC are not required to give up their benefits to accept jobs if those jobs pay less than the family's total AFDC grant. In addition, job training programs available to AFDC recipients are not designed to overcome the cultural and language barriers or to meet the special employment training needs which most refugees have.

On July 1, 1985, the State of California began implementing a three-year statewide refugee demonstration project (RDP). The RDP is designed to test whether the removal of refugee employment disincentives found in the AFDC program will result in more refugees becoming employed and to test the effect of increased employment experience upon refugee self-sufficiency. The project intends to (1) increase the participation of refugees in employment services and training programs specifically designed for refugees; (2) increase refugees' potential for self-sufficiency by allowing them a transition into entry-level, full-time employment without forfeiting the cash grant and other benefits; and (3) reduce long-term program costs through grant reductions as a result of employment.

At the inception of the project, refugee cases which were on AFDC and in which the principal wage earner or caretaker relative had been in the United States for 24 months or less (as of July 1, 1985) were converted from AFDC to the RDP and are required to participate in the project. Newly applying refugee cases in which the principal wage earner or caretaker relative has been in the U.S. for 30 months

or less at the point of application (and who would otherwise be eligible for AFDC) are also being aided under the RDP.

Generally RDP participants are eligible for the same level of cash assistance that they would receive under AFDC, but are subject to the requirements of the RDP, which are similar to those for RCA.

The major problems addressed by the RDP are as follows:

-- In general, refugees are not using AFDC as a means of temporary support to be relied on for only a short period of time while they seek self-sufficiency. Instead, refugees become caught in a protracted spell of cash assistance dependence, gaining little or no work experience. The RDP takes time-eligible refugees out of the AFDC program.

-- Persons receiving assistance under AFDC are not required to accept a job that pays less than their grant. In order to be eligible for a cash grant, RDP participants are required to accept any appropriate offer of employment and may not quit a job without good cause. Employment that pays less than the cash grant (after disregards and allowable expenses) is not considered to be good cause under the RDP since supplementary assistance is provided up to the cash grant level.

-- Persons on the AFDC Unemployed Parent (AFDC-UP) program are ineligible for a cash grant if they work more than 100 hours per month. RDP participants are allowed to work more than 100 hours per month, and supplementary assistance up to the level of the cash grant is available if they meet all other eligibility and income/resources tests.

-- Refugees in the Federal AFDC-UP program are required as a condition of receiving a cash grant to participate in the Work Incentive (WIN) job training programs which may not be designed to deal with refugee cultural and language barriers and/or unique employment services needs. RDP participants are not required to participate in the WIN program. Instead, they are mandatorily referred to refugee-specific employment programs and/or other appropriate training as part of an approved employability plan. Failure to participate in appropriate training or to accept appropriate employment without good cause results in sanctions. These sanctions are the same as for AFDC recipients.

The State of California has provided the following preliminary data on the RDP pertaining to the quarterly period from 7/1/85 through 9/30/85:

-- 5,207 cases totaling 23,001 individuals were enrolled in the RDP as of 9/30/85.

-- Of the 23,001 participants in the RDP, 9,867 were 18 years of age and above; 13,134 were under 18 years of age.

-- Of the RDP participants, 3,391 were enrolled in English language training, 306 were enrolled in job training, 2,776 were receiving employment-related services, and 146 were receiving other support services.

-- During the quarter, 55 clients had entered employment and 58 had been sanctioned.

The Oregon Refugee Early Employment Project (REEP)

The State of Oregon estimates that it currently takes from 24 to 30 months for refugees in the Portland metropolitan area to find stable employment which produces self-sufficiency. Faced with an average unemployment rate over the past several years of approximately 10 percent (seasonally adjusted) and a perception of the public assistance system as an entitlement program, most refugees receiving aid under the refugee cash assistance (RCA) program have remained on that program for the full 18-month period of eligibility.

The Oregon Refugee Early Employment Project (REEP), which began September 16, 1985, integrates the delivery of cash assistance with case management, social service, and employment service functions within the private, not-for-profit sector in an effort to increase refugee employment and reduce reliance on cash assistance by refugees. Encompassing a tri-county area surrounding Portland, where 85 percent of all refugees in Oregon initially settle, REEP aims to place: (1) 75 percent of all employable participants in full-time, permanent employment within 18 months of their arrival in the U.S.; (2) 50 percent of employable participants within 12 months of their arrival; and (3) 25 percent of employable participants within 6 months of their arrival -- reducing the aggregate 18-month dependency rate for these clients from 80 percent to an estimated 50 percent.

The three-year project serves needy refugees who do not meet the AFDC or SSI categorical requirements (e.g., members of two-parent families, couples without children, and single individuals) during their initial 18 months in the United States. The target population includes both new arrivals and secondary migrants. Refugees who normally are eligible for assistance under AFDC continue to be eligible for that program and will not participate in REEP.

The Refugee Early Employment Project has the following major features:

-- The voluntary resettlement agencies provide cash assistance to participants, and provide reception and placement and case management services in cooperation with English language trainers and job service providers.

-- The job service providers, voluntary agency case workers, and English language trainers work as a team in doing assessments, developing employability plans, making job placements, and conducting follow-up activities.

-- Access to training opportunities and job placements is provided to all participants in accordance with a refugee's needs and skills.

-- REEP payment standards are similar to those in the AFDC program although adjustments are made for household composition and for participation in a work experience program, on-the-job training program, or employment. In addition, a small cash incentive is provided to each participant attending training classes each month with no unexcused absences.

-- REEP is structured to assure progressive employment preparation of clients as well as progressively increasing incentive rewards for client movement toward independent employment.

-- Penalties range from warnings to loss of incentives earned to loss of portions of, or all of, the cash assistance payments for individuals who show a repeated unwillingness to cooperate with employment efforts.

-- REEP is replacing the programs of RCA and RMA, which will not operate in the tri-county area.

One month after REEP implementation, the State of Oregon has provided the following data:

-- 21 cases involving 53 individuals have been enrolled in the project.

-- Lutheran Immigration and Refugee Service has resettled nine refugees; U.S. Catholic Conference has resettled 32 refugees; and Church World Service has resettled 12 refugees under the project.

-- Of the 53 participants, 46 (87 percent) are Southeast Asian and seven (13 percent) are non-Southeast Asian.

-- Of the 53, 15 are secondary migrants and 38 are new arrivals.

-- Of the 53, one has moved out of the area and another has been transferred into the AFDC program. Therefore, there are currently 51 participants.

-- Thus far, 26 adults are participating in REEP. Nine have been referred to English language training, one has gone to pre-employment training, five are involved in employment services, including job search, and one refugee has been placed in employment.

Conclusion

Because the California and Oregon demonstration projects have been implemented so recently, sufficient data are not available from which to draw conclusions or make recommendations respecting changes in the refugee program.

ORR will continue to advise Congress of progress reported by the California and Oregon projects, which are scheduled to continue for three years, and will continue to advise Congress of other developments under the Wilson/Fish Amendment.

Question. What progress can you report on these projects?

Answer. It is too early in the life of either project to make definitive statements about progress. Both projects are on target as far as operational requirements are concerned (enrollment of refugees, appropriate rules and procedures established and communicated to governmental offices, service providers, participating refugees, etc.). The expected results, reduction in costs and reduced dependency rates, should be evident to some degree after the first year, and to a greater degree after the second year of operation.

Question. Have other States expressed an interest in alternative projects?

Answer. ORR has approved a pre-application submitted by Massachusetts and the Refugee Coordinator for Washington has expressed an interest in developing a demonstration project.

CASH AND MEDICAL ASSISTANCE - EFFECT OF SEQUESTERING

Question. Of the $428 million appropriated for the Office of Refugee Resettlement (ORR) for FY 1986, $18.4 million would be sequestered. ORR is planning to meet this shortfall in part by limiting reimbursement for cash and medical assistance from 36 months to 31 months, beginning March 1, 1986, for the remainder of FY 1986.

How much is this expected to save?

Answer. Of the $18,398,000 required for sequestration, $11,643,000 came out of cash and medical assistance reimbursements (under Gramm-Rudman-Hollings, programs and activities must be reduced by 4.3 percent across-the-board, rather than a selective reduction that would reduce an appropriation's bottom line by 4.3 percent). The reduction from 36 to 31 months' reimbursement will save the $11,643,000 required by sequestration.

Question. Have the States been notified of this proposal? What is their reaction?

Answer. The States were notified in a letter dated January 23, 1986, from Phillip N. Hawkes, ORR Director, to all State refugee coordinators. ORR has received no adverse reactions from the States, and all States did comply and implemented the 31-month policy effective March 1, 1986.

FISH/WILSON DEMONSTRATION PROJECTS - SEQUESTRATION

Question. Counties with large refugee populations in California are currently participating in the Refugee Demonstration Project set up under the Fish/Wilson Amendment which allows for alternate means of providing cash and/or medical assistance to reduce welfare dependency. Refugees participating in this program are currently eligible for assistance similar to refugee cash assistance for up to 36 months.

Will this period be reduced to 31 months beginning March 1?

Answer. To avoid disrupting obligations already made for the demonstration project, ORR will not subject refugees participating in California's Refugee Demonstration Project (RDP) to the 31-month policy.

TARGETED ASSISTANCE - RESCISSION

Question. The Administration is seeking a rescission of $47.9 million in FY 1986 Targeted Assistance funds for heavily impacted areas, and no Targeted Assistance funds for FY 1987. As you know, Targeted Assistance has been of particular concern to the Congress. The House-passed H.R. 1452 would authorize a line item of $50 million annually for Targeted Assistance. (More recently, a dispute over OMB's proposal to withhold $11.5 million of FY 1985 Targeted Assistance funds has been overruled to date by both GAO and the U.S. District Court for the Northern District of California.)

How do you explain the discrepancy between the Administration's view that these funds are not necessary with the view of many in Congress that they are?

Answer. The TAP funding is awarded based on the refugee and entrant population that arrived from 1980-1982, years of highest arrivals. These funds are in addition to regular social service funding awarded to the States each year based on the three-year eligible population.

The major justification for Targeted Assistance was that, during the peak years of 1980-1982, the influx of refugees overwhelmed the capacity of service providers to provide services. Furthermore, funding under the regular social services program would have been insufficient to adequately respond to the backlog of service needs which, if not met, would further exacerbate welfare dependency. Thus, the Targeted Assistance program was a short-term, locally-administered program to address particular needs in the communities most affected by the refugee influx.

ORR's on-site monitoring in California has shown that much of the Targeted Assistance funds have not substantially reduced welfare dependency among the AFDC-UP population in the State. This is the population which constitutes the burden qualifying the State to receive over $65 million in Targeted Assistance funds.

Present FY 1985 funding will be sufficient in most areas to fund services through March 1987. In addition, a number of States are likely to have unexpended funds at that time. Thus, with funds presently available, local administering agencies will have had more than 3.25 years of programming with which to address special needs of refugees in their respective communities. Further funding is therefore seen as unwarranted at this time.

Question. Your budget justification (p. 306) states that FY 1985 funds "will be adequate to continue assistance through March of 1987."

Answer. That is correct.

Question. How much additional funding would be required to continue program funding through the end of FY 1987?

Answer. Approximately $30,500,000.

VOLUNTARY AGENCY PROGRAMS

Question. The budget justification (page 30) states that "approximately 4,000 refugees arriving in FY 1987 will qualify to participate in the program." This is the same number for FY 1986, FY 1985, and FY 1984.

What qualifies a person for this program?

Answer. Services and benefits provided under the matching grant program may be extended to any properly documented, newly arrived refugee or refugee family unit with whom a qualified voluntary agency or its affiliate has an on-going relationship established through the Cooperative Agreement, and who has been placed in a city in which the grantee has an affiliate or local office.

Within these guidelines, agencies use their own criteria for determining which refugees they will serve in this program.

Question. How many persons participated in this program in FY 1984, 1985 and 1986?

Answer. In FY 1984, about 7,000 refugees participated in the program. In FY 1985, approximately 5,300 refugees were served, and in FY 1986 approximately 5,100 refugees are projected to participate in the program.

Question. Can you give a breakout by refugee group?

Answer. An estimate based on geographic origin of refugees to be served in FY 1986 is as follows: 50 percent European; 19 percent mid-Eastern; 12 percent African; 10 percent Soviet; and 9 percent Southeast Asian.

EDUCATIONAL ASSISTANCE

Question. Once again, your budget proposes to eliminate educational assistance for children, both in FY 1986 through a rescission of $15.9 million, and in FY 1987 through a zero funding request.

Do you have any evidence that the States no longer need these funds?

Answer. Since 1980, over $100 million has been provided to help school districts meet the initial cost of responding to the special needs of refugee pupils. As we have said, refugee flows peaked in fiscal years 1980-1982, and in recent years the flows have been much smaller. The preponderance of new arrivals qualify for family reunification and are settling in communities in which the school systems have already been helped to build capacity for meeting the needs of these refugee children. Refugee pupils are now an established part of the school population, and many refugees are now working and paying taxes to help support local school systems. Therefore, we consider that the need and justification for the type of special funding that has been provided in the past no longer exists.

Question. What guarantees can you offer that school districts will be able or willing to continue to meet the special needs of refugee elementary and secondary school children?

Answer. We are confident of the ability and commitment of the schools to continue to meet the special needs of refugee school children just as they meet the wide variety of needs -- language and other needs -- of other, non-refugee children. School districts have already developed the bilingual programs used by incoming refugees, and these existing programs will continue to offer the support needed. While we are not able to provide any guarantee since educational policies and programs are determined locally, we feel that the established record of schools is the best assurance of their future commitment.

ORDERLY DEPARTURE FROM VIETNAM

Question. In FY 1986, the refugee admissions allocation was 67,000. Of this amount, 8,500 admissions were allocated to the Orderly Departure Program from Vietnam (ODP).

How many entrants actually entered the United States under this allocation in FY 1986?

Answer. During the first five months of FY 1986, 3,458 refugees have entered the United States through the Orderly Departure Program from Vietnam. We expect to reach the ceiling figure of 8,500 in FY 1986.

Question. How many of these entrants were children? How many were school-age children?

Answer. Figures are not available on the exact number of children entering under the ODP. However, in FY 1985, 41.1 percent of the arriving Vietnamese refugees were under age 18, and 32.7 percent of the arriving Vietnamese refugees were aged 6 through 17. If the ODP arrivals resemble this profile, we can expect about 3,500 children in FY 1986, with 2,800 being of school age.

Question. How many admissions will be allocated to ODP in FY 1987?

Answer. The projected admissions level which we use for planning and budgeting purposes under the ODP is 10,000 in FY 1987. The actual ceiling will be established during the consultation hearings in September 1986.

Question. How many actual admissions do you project under this allocation?

Answer. At this time, the projected admissions level under the ODP in FY 1987 is the same as the planning figure: 10,000.

Question. How many children (total) and school-age children do you project will enter the U.S. under this program in FY 1987?

Answer. Using the same assumptions about the age structure of the arriving ODP refugees as above, we would expect about 4,100 children under age 18, of whom 3,300 would be of school age.

Question. Will the elimination of educational assistance to children in FY 1987 increase the burden on impacted school districts by these Vietnamese entrants?

Answer. We would not characterize this as a burden. With the more than $100 million that has been provided for schools since 1980, school districts have been helped to build the capacity for the education of refugee children. In the last few years refugee flows have decreased substantially; most of the arrivals are for family reunification, joining relatives in areas in which the schools are now experienced in aiding the refugee children; and many refugees are self-supporting and paying State and local taxes which help to support their schools. In light of these considerations, we believe that the special Federal refugee funding is no longer justified.

LONG-TERM STUDIES

Question. For many of your proposed reductions in FY 1987 such as the elimination of educational assistance to children and targeted assistance, you state that many of the refugees who entered the U.S. in the early 1980s (for whom these programs were specifically designed) have since been mainstreamed into the general population, and are employed, tax-paying citizens.

Have you conducted any long-term studies/evaluations of refugees who are past the three-year eligibility of your programs and their impact on the community?

Answer. ORR's annual telephone survey of Southeast Asian refugees includes refugees who have been in the United States for more than three years, as well as those who have arrived more recently. In addition, ORR conducted a study in 1983 in several localities heavily impacted by refugees. The study found that the negative effects of initial impact were often replaced by positive effects. For example, some neighborhoods were rejuvenated by the newcomers who opened businesses and reinvigorated community life. Some schools, suffering from declining enrollments, were kept alive by refugee arrivals. Some businesses needed the pool of labor represented by the newcomers. Finally, the initial cost to local institutions was largely covered by Federal refugee program dollars.

Question. Are they welfare dependent? What percent?

Answer. In October 1984, the Annual Survey showed that 38.8 percent of the Southeast Asian refugees who had arrived from 1975 through early 1981 were living in households receiving cash assistance. The typical recipient household in this survey had 5.1 members, of which 1.2 were wage earners. This means that the typical recipient household was partially rather than fully dependent on cash assistance.

Question. Are they employed? What percent?

Answer. In the October 1984 Annual Survey, the labor force participation rate for refugees who arrived from 1975 through early 1981 was 74.4 percent (compared with 64.6 percent for non-refugees), and their unemployment rate was 9.0 percent (compared with 7.0 percent for non-refugees).

Question. Are they taxpayers? What percent?

Answer. In 1983, the most recent year for which tax data are available, Internal Revenue Service figures show that $99.2 million was paid in Federal income taxes by the Southeast Asian refugees who arrived from 1975 through 1979. In that year, 77 percent of the tax returns filed by this group of refugees showed incomes high enough to be subject to Federal income taxes.

SOCIAL SERVICES

Question. Under "Program Accomplishments" in your budget justification (page 21), you state that Mutual Assistance Associations (MAA) have been established as a "resource and participant in the resettlement process" and as a provider of social services. A significant source of funding for MAAs is provided in Targeted Assistance and social services programs.

Please provide for the record the amounts of funding MAAs received from the Targeted Assistance program and the State-administered social services program for FY 1985, 1984 and 1983.

Answer. Total ORR funding for MAAs for FY 1982-1985 was $10,050,109.

FISCAL YEAR 1985:

Total of State allocations for MAAs: $3,050,000.

Additional technical assistance was given to refugee/entrant MAAs through a national contract funded at $300,000.

FISCAL YEAR 1984:

Total of State allocations for MAAs: $3.3 million.

Forty States and the District of Columbia participated in the MAA incentive allocations program. Twenty-one States provided funding to MAAs in their States. A total of 53 MAAs received funding from their States to provide social services. The remaining 19 States and the District of Columbia requested proposals from MAAs.

Two States set aside a portion of their allocations to provide technical assistance to MAAs. California provided 38 agencies/MAAs with $2,000 each as Mini Planning Grants to enable previously unfunded MAAs to secure assistance in developing concepts and competitive proposals in response to the State's social service RFPs released during FY 1985. The State also set aside $75,000 to purchase technical assistance services for MAAs. The State of Maryland also set aside a portion of its allocations to purchase technical assistance services for the MAAs funded by the State.

FISCAL YEAR 1983 - ORR MAA Initiatives:

Fourteen States were competitively selected to receive supplemental social service allocations to contract directly with MAAs for the provision of social services to refugees and entrants. Five of the fourteen States requested extension of these MAA grants to September 1985, while the other nine States closed out their MAA

grants in 1983-1984. The total funding was $2,624,017, with $917,478 of the amount coming from ORR and $1,706,539 funded by the States.

ORR funded IRAC at $115,000 to provide technical assistance in leadership and program development and management for MAA leaders at eight impacted sites nationwide.

ORR Regional Offices funded eleven MAAs at a total of $169,630 for the provision of technical assistance on leadership and business management and development.

FISCAL YEAR 1982 - MAA Incentive Grants Program: $791,462.

Twelve States were competitively selected to receive supplemental social service allocations to contract directly with MAAs.

Question. Given your proposal to eliminate targeted assistance and cut social services by 32 percent, how much commitment do you anticipate States will have to fund MAAs under these new fiscal constraints?

Answer. ORR, in the proposed Formula for Allocations to States of Fiscal Year 1986 Funds for Social Services for Refugees and Cuban/Haitian Entrants, proposed an MAA Incentive Allocation totalling $1,933,360. If this amount becomes final, States which agree to accept this allocation will provide their proportionate share of this amount to contract with MAAs. Since, in prior fiscal years, many States have elected to utilize funds for MAA contracts from their regular social services allocations, it is anticipated that the MAA incentive allocation will be exceeded in a number of States.

Questions Submitted by Senator Mark Andrews

EMPLOYMENT REDUCTIONS--EFFECT ON SERVICE

Question. It is my understanding that since 1980, the Social Security Administration has reduced its employees by 8,000. At the same time, the number of individuals being served increased by 1.9 million bringing the total number of beneficiaries up to 40 million. Your current budget request calls for a staffing reduction of 3,000 employees. Additionally, a recent GAO report concluded that the majority of Social Security recipients perceive SSA favorably as to the quality of services provided by the Administration. What effect do you foresee the proposed staffing reductions will have on service levels particularly in State field offices?

Answer. We foresee no impact on service levels at the field office or any other level of service.

Staffing reductions will be accomplished through management, procedural and systems changes. As automation and improved procedures are introduced which reduce the number of workyears required to process our workloads, there will be reductions in employment throughout SSA, including in the field offices. However, we expect to maintain or improve service to the public during this

period as a result of the implementation of claims modernization and other more efficient processes.

PROGRESS IN SYSTEMS MODERNIZATION

Question. Last year, a major topic for discussion was the modernization of SSA's computer system. A large part of your justification for staffing reductions was tied to the installation of the new system. How far have we come since last year?

Answer. SSA has continued its progress in the Systems Modernization Plan to overhaul SSA's computer system and move it to a state-of-the-art system capable of providing all services which are required by law and necessary to serve the public. Significant progress has been made toward upgrading SSA's telecommunications system, improving software, moving to direct access data storage, obtaining needed hardware, and improving beneficiary services. Some specific systems achievements in the past year include:

--Upgrading the host computer channels for SSA's current telecommunications network.
--Converting all major master files and their associated intermediate files from tape to direct access storage device technology.
--Testing claims modernization project (CMP) software in 18 pilot offices (in addition to the two original pilot offices in York, Pennsylvania and Baltimore, Maryland which went "live" last March); as of mid-April 1986 live claims are now being taken in all 18 of the new offices.
--Completing adjustment of benefit payment amounts to include 1982 earnings, and making adjustments for 1983 earnings with improvements in timeliness and degree of automation. The adjustment for 1983 earnings was completed 5 months earlier than for 1982 earnings, which means that beneficiaries received increases in their checks 5 months earlier.

INCORRECT DEATH NOTICES AND OVERPAYMENTS

Question. In September 1985, an article appeared in the Washington Post which was illustrative of a number of my concerns, which I expressed during the course of that hearing along with several of my colleagues. I am referring, of course, to the article about a gentleman who--although very much alive--was declared dead by SSA in August 1984. The computer error went uncorrected until September 1985--a period of 13 months--and this in spite of repeated forms and letters sent to SSA and at least two visits to the SSA office. Considering the proposed staffing reductions and if we tie them to the new computer system, are precautions in place that would prevent such an occurrence from happening again?

Answer. Erroneous death termination actions generally result from data errors on source or input documents. For example, we may receive an erroneous report that an individual is deceased; a report could contain an incorrect Social Security number, or a manual action could be misprocessed. While we do have checks in our systems to guard against such occurrences, they are not foolproof; and errors will continue to happen occasionally. We are strengthening these checks and balances as we modernize our systems, and we are improving our ability to match records from external

sources. We are hopeful that these actions will go a long way toward reducing problems such as these.

Question. What about overpayments and the current error rate--do you expect increases here as well?

Answer. We do not expect overpayments or error rates to increase as a result of modernization of SSA's computer system. On the contrary modernization of SSA's systems may help to reduce errors and prevent overpayments. For example, under the modernized system there will be less manual handling of claims and more automated computations, both of which should contribute to increased accuracy. Also, direct input of status changes should help prevent overpayments which result from delays on effectuating such changes in the automated system.

Questions Submitted by Senator William Proxmire

ESTABLISHING ENGINEERED WORK STANDARDS

Question. Last year, in a response to a question submitted for the hearing record, you stated that geographical variations cause difficulties in establishing work standards. However, you acknowledged that there have been no studies to determine the impact of regional differences. Assuming that regional differences would preclude the development of national work standards, wouldn't it then be reasonable to work towards the establishment of regional work standards?

Answer. At present, the establishment of national or regional work standards would be undesirable and untimely. Field work processes are in a state of rapid change due to the time-phased development, testing and national implementation of a modernized, highly automated claims process for SSA's 1,300 field offices and eight processing centers. Once this modernized claims process has been fully developed and put in place nationwide, we could explore the possibility of a pilot study on work standards. We do know, however, that differences exist within regions as well as among regions. For example, the New York region is made up of the metropolitan New York area, plus upstate New York, New Jersey and Puerto Rico--which are diverse in their cultural and demographic makeup and therefore in their service needs. A local office serving a population with lower socioeconomic status, lower education and literacy levels and a high percentage of non-English speaking clients would need to spend more time with each client to provide a high level of service.

Question. In past years, we have discussed your use of standards based on prior experience, so-called "does take" standards, rather than "should take" or engineered standards, for staff budgeting. I understand that the use of "does take" standards permits the inclusion of built in inefficiencies in the work process and could result in allowing more time to perform various workloads than may actually be needed. In view of the need for possible staff reductions imposed by the Office of Management and Budget and the Balanced Budget and Emergency Deficit Control Act of 1985, it would seem appropriate to develop staff needs on the most reliable basis possible. Wouldn't it be possible to begin developing engineered

standards on a test basis at selected locations? It would seem prudent to give them a chance in view of the present fiscal environment.

Answer. It is accurate to say that SSA does not base its budget on uniform engineered standards. However it is important to note that we do not simply accept "does take" times as "should take" times when projecting workyear needs. Rather we analyze actual performance in the base year ("does take") as a starting point, then project changes in production rates based on planned management, procedural and systems improvements, as evidenced by the discussion on pages 183-193 of our budget justification to the Congress. As I have indicated, development of engineered standards would be inappropriate during this present period of rapid change in field work processes.

Question. One way of moving toward engineered standards would be through the establishment of baseline standards which reflect the most efficient processes of some of your productive offices. Would you be willing to try this approach on a pilot basis to see whether more realistic time standards could be developed for budget purposes?

Answer. As I have stated, it is inappropriate to try to develop engineered standards when we are in the midst of rapid change in field processes due to the implementation of a modernized highly automated claims process. However, we have not dogmatically precluded consideration of the use of engineered standards at some time in the future. Once our modernized claims process has been fully developed and put in place nationwide, we could consider a pilot study, with a view toward developing a benchmark or guide against which field managers could measure their operations. However, the variable demographics of each office would preclude adoption of the "optimum" processing environment by all field offices. A secondary benefit would be obtaining experience in setting engineered standards in SSA and determining their practical utility. I would point out that while we are not in a position now to develop or establish standards, we have institutionalized the practice of exchanging information on management practices in district offices. We have observed that highly productive offices show a consistent set of features that we've disseminated for consideration by all offices, in order to help speed delivery of service to the public and permit more efficient use of staff resources.

Question. The Social Security Administration is currently involved in a 17,000 staff-year reduction. We have seen considerable information on the plans and progress being made, but there is always the concern that service to the public may be reduced along with staff levels. GAO, in a recent report on productivity in the Atlanta Region, pointed out that some offices served as many claimants as others, while using less staff. Further, there appeared to be little difference in service quality between these offices. Would not it be appropriate to make an examination of the balance between workload and staff, on a nationwide basis, in order to provide SSA a means to target offices that could accommodate staffing reductions without affecting public service? Would this not be a valuable tool in your approach to achieving planned reductions?

57-852 O—86——36

Answer. The staffing reductions which it is SSA's goal to achieve will come about as a result of management, procedural and systems changes to be implemented on a nationwide basis. As we move into implementation of these improvements, field office work processes are in a state of rapid change, and office-by-office comparisons may not provide meaningful information. When we reach a more stable environment, it may be appropriate to look at staffing-to-workload ratios, keeping in mind that demographic differences may continue to result in differing service needs in our client population.

Question. In view of the systems modernization project, it would seem that your field activities in the future would become more standardized and consistent throughout the country. The time needed to process a routine claim in an office in California should not differ to any significant extent from the time needed to process a similar claim in Pennsylvania. I am talking here of claims where State laws do not significantly affect processing. In the past, you indicated that work standards are difficult to use because of demographic factors, differences in the workforce, the systems modernization project, and frequent changes in law and regulations. Once systems modernization is in place, wouldn't these obstacles to using engineered work standards be eliminated?

Answer. Once the claims modernization project has been implemented nationwide, we will be in a position to consider a pilot study on work standards. Naturally, implementation of claims modernization will not eliminate differences among localities in demographic factors and workforce.

CARRYOVER OF EARMARKED AUTOMATION FUNDS

Question. Last year you estimated a carryover of $81,926,000 in your automated data processing and telecommunications account from 1985 to 1986. Your actual carryover was $217,103,000. Can you tell us why your original estimate was so wide of the mark?

Answer. The large carryover of funds reflects the fact that it is difficult to project with precision how much will be obligated in any particular fiscal year in a long-term modernization effort. There are several reasons for the difference between the original estimate and the actual carryover from FY 1985, including delays in the procurement process, awards lower than estimated and deferrals based on revised project schedules.

Much of the variance was due to delays in the procurement process for projects such as the following:

- o The Data Communication Utility communications processors (bidder protests delayed the award).
- o The Data Base Architecture project (unacceptable bidder responses to our solicitation).
- o Data Exchange and Inquiry Response Logical Application Groups (unacceptable bidder responses).

Other projects were affected by various factors:

- o Use of in-house resources (rather than contracts) to develop software for the Claims Modernization Project.

- o Deferral of upgrades to (and acquisition of) various host processors to coincide with new systems workload requirements.
- o Awards for various projects (office automation, software development contracts) at lower-than-estimated cost.

In addition to these Systems Modernization Plan projects, the plans for acquisition of new telephone systems in FY 1985 were affected by the following factors:

- o Deferral of the large SSA headquarters telephone system award due to the complex contractural and technical issues involved in this acquisition.
- o Delays in acquiring several program service center telephone systems due to continued construction and extension of the procurement process.
- o Deferral of some field office purchases until evaluation of initial acquisitions is completed.
- o Awards for some projects were lower than estimated.

DEBT COLLECTION EFFORTS

Question. Last year you estimated debt collections of $1.361 billion in 1986. Your current estimate for 1986 has fallen to $1.167 billion. You also are cutting the Federal workyears below your original 1986 estimate. If this is truly a cost effective program, as your justifications show it is, why are you cutting back your efforts in this area?

Answer. The reduced 1986 collection estimate is a result of two factors. First, SSA accelerated the earnings enforcement process in 1985, moving some anticipated collections for 1986 into 1985. Second, the Commissioner's initiative to reduce earnings-related overpayments was more successful than originally anticipated. The lower level of detections that resulted caused us to lower our 1986 collection estimate. Similarly, the reduced administrative cost estimate for 1986 reflects administrative improvements rather than a cutback in our debt collection efforts. In addition to the timing of the enforcement process and fewer earnings-related overpayments, increased automation of the debt collection process and the planned implementation of the Treasury lockbox remittance network to process SSA's receipt and deposit operations allow SSA to reduce the workyears needed for debt collection operations without impeding the efficiency of the program.

INCREASED EXPENDITURES FOR EQUIPMENT

Question. Last year you estimated expenditures of $116,905,000 for equipment in fiscal year 1986. You now project equipment costs of $126,011,000 in 1986 despite a cutback in total administrative expenses below your original request because of the Gramm-Rudman-Hollings Act. Can you tell us what pushed your equipment expenditures up by almost $9 million?

Answer. The net increase of $9.0 million results from three major actions. A reassessment of purchases related to the Information Technology Systems budget for ADP equipment resulted in a plus $18.7 million change. This increase was partially offset by

decreases in other equipment costs. A reassessment of purchases related to the Claims Modernization Project resulted in a decrease of $4.0 million. In addition, an unspecified reduction of $5.3 million was taken as part of SSA's overall plan to live within constraints established under the Gramm-Rudman-Hollings Act.

INCREASED EXPENDITURES FOR INSURANCE CLAIMS AND INDEMNITIES

Question. Another area of significant cost growth over the last 12 months has been insurance claims and indemnities. Your original 1986 estimate of $683,000 has jumped to a current estimate for 1986 of $2,028,000. Can you tell us why?

Answer. The increased costs of insurance claims and indemnities represents the added cost pursuant to passage of P.L. 99-80, signed August 5, 1985, which made Equal Access to Justice Act (EAJA) reimbursements to attorneys a permanent operating cost. EAJA provides that a court may award attorney fees and certain other expenses to a prevailing claimant when the government position was not substantially justified. Our original FY 1986 estimate covered costs only for court awards still pending when the original law expired at the end of FY 1984. With the passage of P.L. 99-80, we needed to budget for court awards on an ongoing basis, requiring an additional $1.4 million for FY 1986.

SCREENING REFUGEES FOR "AIDS"

Question. Mr. Hawkes, on page 3 and 4 of your prepared statement you talk of medical screening and follow-up. You mention a tracking and notification system for refugees with tuberculosis, venereal disease and leprosy. One illness not specifically mentioned is acquired immune deficiency syndrome (AIDS). Do you have any plans to screen refugees for the AIDS virus?

Answer. At present, we do not screen refugees for HTCV-III "AIDS" virus. This policy is consistent with the policy that is now observed for other immigrants. However, if the present immigration policy changes, we would implement the change in the refugee program as well.

Question. Mr. Hawkes, on pages three and four of your prepared statement you talk of medical screening and follow-up. You mention a tracing and notification system for refugees with tuberculosis, venereal disease and leprosy. One illness not specifically mentioned is acquired immune deficiency syndrome (AIDS).

Do you have any plans to screen refugees for the AIDS virus.

Answer. At present, ORR has no plans to screen refugees for HTLV-III "AIDS" virus.

Questions Submitted by Senator Lawton Chiles

STAFFING IMBALANCES AND WAITING TIMES

Question. You claim you can make the staffing cuts proposed without adversely affecting service to the public. Yet I understand offices, particularly in South Florida, are understaffed to the

point that waiting times for claims representatives are exceeding 45 minutes. Atlanta regional officials indicate that these personnel shortages cannot be addressed without forced transfers of personnel from other parts of the region. Already the Southeast is handling over 40 percent of the national caseload with 28 percent of the personnel. In view of these problems, shouldn't you be adding staff rather than cutting back?

Answer. When we become aware of local staffing problems which cannot be resolved at the regional level, we act to correct them. For example, we recently sought exception from a temporary Departmentwide hiring freeze in order to permit hiring in certain regions where reports showed excessive waiting times were occurring in SSA field offices. One of those areas was South Florida. In March, the Atlanta region was granted exception to immediately hire up to 30 employees to help alleviate the Florida problem. Since that time the Departmentwide freeze has been lifted, and SSA regions are operating within their FTE allocations. Atlanta's allocation will allow it to replace all of its losses for the remainder of this fiscal year.

I am not familiar with the statistics you cite on caseload and personnel in the Southeast; however, I can tell you that regional staffing allocations are not based strictly on the total volume of work to be processed. Because of demographic factors and other differences in the nature of work at the State and local levels, there are variations in unit times in different parts of the country which must be considered when allocating staffing resources. For example, varying educational levels in different parts of the country affect the amount of assistance required by claimants in completing claims actions, and thus affect unit times. The point I am trying to make here is that if a region's share of the total field employment allocation is less than its share of the total volume of work to be processed, this does not necessarily mean that the region is not adequately staffed or that other regions are overstaffed in relation to the work they have to do.

As our employment needs continue to change as a result of claims modernization and other improvements in the way we do business, I agree that we must manage our resources very carefully in order to avoid imbalances in geographic areas and in the kinds of positions we fill. We are committed to improving our productivity without adversely affecting service to the public.

Question. How do you propose to deal with the imbalances as the Sunbelt and South Florida grow?

Answer. If the overall amount of work in South Florida and the Sunbelt grows beyond the capacity of SSA offices in these areas to handle the work, then these areas will be allocated a greater share of the total field office employment resources. Regional staffing allocations are derived, in part, from estimates of expected workloads for each region, which are made by SSA's statisticians based on trends over the past several years. Unit times is another factor considered in allocations. Periodically throughout the year these allocations are reviewed to determine if, based on actual experience, any adjustments are needed. If actual workload receipts and processing times by region deviate from the budget plan we will take corrective actions, including reallocation of resources.

Through these periodic adjustments we deal with changes in workload patterns on an ongoing basis, to prevent serious imbalances from occurring.

Question. What is the average waiting time nationally for seeing a claims representative as opposed to the waiting time for seeing a service representative?

Answer. We do not have information about the waiting time nationally for seeing a claims representative as opposed to the waiting time for seeing a service representative.

STREAMLINING STAFF FUNCTIONS

Question. On page 192 of your appropriations justification to this Committee, you refer to planned savings of 420 workyears in FTE reductions from "streamlining staff functions." What does this mean? Would you spell out exactly what you plan to streamline and how?

Answer. "Streamlining staff functions" refers to our initiative to reduce staff/support positions. These positions are identified as staff performing budget management, personnel administration, material resource management, policy formulation, and other administrative services. It does not include employees who are directly involved in workload processing.

A Contribution Analysis Survey (CAS) was conducted of all staff/support functions in SSA to determine potential areas for streamlining. Rather than implement an across-the-board percentage reduction, we are using the survey results to assist us in targeting staff/support reductions. We are now involved in developing proposals for achieving savings in staff/support positions.

CLERICAL SHORTAGES

Question. A recent report of the General Accounting Office indicates that recruits for the claims representative position come from Social Security's clerical and technical staff. This has resulted in a shortage of clerical staff and in managers having to do their own typing in the field offices. It seems you have highly-paid, professional staff doing clerical work while clients wait for service. At the same time, GAO documents the continued downward trend in clerical workers--942 people, a decline of 19 percent from October 1982 to September 1984, followed by a reduction of 275 clericals in 1985. How efficient is it to have highly-paid professionals do their own typing? Will you be doing a survey of managers to determine the effect of clerical shortages in their offices?

Answer. We have read the GAO report ("SOCIAL SECURITY: Actions and Plans to Reduce Agency Staff") sent to Senator Weicker, Senator Proxmire and Senator Chiles on March 17, 1986. That report indicates accurately that as a part of overall staff reductions, there have been reductions in clerical staff. We do not find in that report conclusions that there is a shortage of clerical staff, that clerical shortages arise from the recruitment of clerical staff for claims representative positions, or that clerical shortages

result in managers having to do their own typing. In fact we do not believe that there is a shortage of clerical staff in SSA's field offices. That's not to say we don't have temporary staffing imbalances affecting individual offices (for example, as a result of turnover) which could result in a particular office not having enough clerical help. However, our Regional Commissioners have the responsibility to identify such situations and are given flexibility, within an overall employment allocation for the region, to hire the mix of employees needed and to focus that hiring where necessary to correct temporary imbalances.

Questions Submitted by Senator Dale Bumpers

ENERGY PROGRAM IN ARKANSAS

Question. In FY 1986, what is the Arkansas share of Low Income Energy Assistance funds, presequester and postsequester, in percentage and in total amount?

Answer. Arkansas' share of Low Income Home Energy Assistance funds presequester was 0.73 percent or $15,302,982, and postsequester was 0.67 percent or $13,513,731.

Question. Were there sufficient funds for all qualified grantees during the 1985-86 heating season in Arkansas? Which States had sufficient Low Income Energy Assistance funds available this winter?

Answer. Arkansas expected to receive $15,302,982 for its Low Income Home Energy Assistance Program (LIHEAP) in FY 1986. As a result of the reduction in the LIHEAP appropriation due to the Balanced Budget and Emergency Deficit Control Act of 1985, Arkansas' allotment was reduced to $13,513,731. The Arkansas State Office applied this reduction equally among the local agencies and monitored the local level expenditures on a daily basis. The State offices closed all agencies on February 11, 1986, or 7 weeks earlier than planned, when funds were exhausted.

This year, some other States found themselves in similar situations for the same reason. We anticipate there will not be a problem next year. The President's budget meets the Balanced Budget and Emergency Deficit Control Act's target for FY 1987 and requests $2.1 billion for LIHEAP, i.e., the amount available in FY 1986 prior to sequestration.

DECISION ON ALLOCATING GRAMM-RUDMAN REDUCTIONS IN ENERGY PROGRAM

Question. Explain the basis for your decision on allocating the 4.3 percent sequester among the States? Which States received an 11.7 percent sequester? Which States received no sequester?

Answer. The Gramm-Rudman-Hollings reduction was treated as a reduction in the LIHEAP appropriation. The funds remaining after sequestration were distributed according to the LIHEAP allocation formula. Section 2604(a)(2)(A)(ii) of the LIHEAP statute directs that no State shall receive less in FY 1986 than it would have received in FY 1984 (i.e., under the allocation formula prior to its

being changed by the Human Services Reauthorization Act of 1984) if the appropriation had been $1.975 billion.

Twenty-three States are held harmless at their current level. Thus, the $90.3 million Gramm-Rudman-Hollings reduction was distributed over the remaining 27 States, the District of Columbia, and the territories. Grants to the territories, including Puerto Rico, are calculated as a percentage (roughly 0.14 percent) of the funds available for grants. The allocation for the territories therefore decreased by 4.3 percent under Gramm-Rudman-Hollings. The allotments of the remaining 27 States and the District of Columbia decreased by percentage amounts ranging from 4.3 percent to 11.7 percent, as shown in the table which follows. Grants to Indian tribes generally decreased by the same percentage as did the allotment to the State(s) in which the tribe is located.

LOW INCOME HOME ENERGY ASSISTANCE PROGRAM

GRAMM-RUDMAN CUTS IN DOLLARS AND PERCENTAGE OF THE CUT

FY 1986

STATE	GROSS ALLOTMENT BEFORE GRAMM-RUDMAN CUTS	GROSS ALLOTMENT AFTER GRAMM-RUDMAN CUTS	AMOUNT OF DECREASE	PERCENTAGE OF DECREASE
Alabama	$20,055,090	$17,710,215	$2,344,875	11.7%
Alaska	10,815,202	10,815,202	0	0.0%
Arizona	9,698,881	8,564,871	1,134,010	11.7%
Arkansas	15,302,982	13,513,731	1,789,251	11.7%
California	107,589,719	95,010,144	12,579,575	11.7%
Colorado	31,692,305	31,692,305	0	0.0%
Connecticut	41,343,730	41,343,730	0	0.0%
Delaware	5,988,766	5,731,249	257,517	4.3%
DC	6,725,747	6,436,540	289,207	4.3%
Florida	31,733,142	28,022,848	3,710,294	11.7%
Georgia	25,089,914	22,156,358	2,933,556	11.7%
Hawaii	2,134,629	2,134,629	0	0.0%
Idaho	12,362,111	12,362,111	0	0.0%
Illinois	121,420,693	116,199,597	5,221,096	4.3%
Indiana	54,545,812	52,200,340	2,345,472	4.3%
Iowa	36,719,670	36,719,670	0	0.0%
Kansas	18,060,013	17,283,432	776,581	4.3%
Kentucky	30,886,082	28,183,302	2,702,780	8.8%
Louisiana	20,503,252	18,105,976	2,397,276	11.7%
Maine	26,784,147	26,784,147	0	0.0%
Maryland	37,470,649	33,089,516	4,381,133	11.7%
Massachusetts	82,701,153	82,701,153	0	0.0%
Michigan	114,998,162	110,053,236	4,944,926	4.3%
Minnesota	78,271,456	78,271,456	0	0.0%
Mississippi	17,194,125	15,183,758	2,010,367	11.7%
Missouri	50,087,155	47,778,052	2,309,103	4.6%
Montana	14,499,970	14,499,970	0	0.0%
Nebraska	18,159,286	18,159,286	0	0.0%
Nevada	4,555,275	4,022,665	532,610	11.7%
New Hampshire	15,653,641	15,653,641	0	0.0%
New Jersey	86,626,243	80,250,915	6,375,328	7.4%
New Mexico	11,920,234	10,722,624	1,197,610	10.0%
New York	250,682,526	250,682,526	0	0.0%
North Carolina	44,221,026	39,050,627	5,170,399	11.7%
North Dakota	15,751,355	15,751,355	0	0.0%

LOW INCOME HOME ENERGY ASSISTANCE PROGRAM

GRAMM-RUDMAN CUTS IN DOLLARS AND PERCENTAGE OF THE CUT

FY 1986

STATE	GROSS ALLOTMENT BEFORE GRAMM-RUDMAN CUTS	GROSS ALLOTMENT AFTER GRAMM-RUDMAN CUTS	AMOUNT OF DECREASE	PERCENTAGE OF DECREASE
Ohio	113,925,355	105,815,466	8,109,889	7.1%
Oklahoma	18,434,747	16,279,324	2,155,423	11.7%
Oregon	24,562,876	24,562,876	0	0.0%
Pennsylvania	134,653,488	134,653,488	0	0.0%
Rhode Island	13,613,082	13,613,082	0	0.0%
South Carolina	15,927,829	14,065,519	1,862,310	11.7%
South Dakota	12,792,859	12,792,859	0	0.0%
Tennessee	32,329,050	28,549,081	3,779,969	11.7%
Texas	52,793,359	46,620,669	6,172,690	11.7%
Utah	14,727,489	14,727,489	0	0.0%
Vermont	11,732,961	11,732,961	0	0.0%
Virginia	41,694,856	39,901,975	1,792,881	4.3%
Washington	40,402,548	40,402,548	0	0.0%
West Virginia	18,737,280	17,931,576	805,704	4.3%
Wisconsin	70,455,549	70,455,549	0	0.0%
Wyoming	5,896,563	5,896,563	0	0.0%
Am. Samoa	45,265	43,319	1,946	4.3%
CNMI	34,470	32,988	1,482	4.3%
Guam	99,244	94,976	4,268	4.3%
Puerto Rico	2,463,499	2,357,563	105,936	4.3%
TTPI	104,642	100,142	4,500	4.3%
Virgin Isl	93,846	89,810	4,036	4.3%
	$2,097,765,000	$2,007,561,000	$90,204,000	

ALLOCATION OF ENERGY OVERCHARGE FUNDS

Question. How much money will each State receive pursuant to the settlement of the Exxon oil overcharge case? Under the Exxon decision, how will the States divide the monies received among the conservation grant programs and LIHEAP? Will the allocation be within the discretion of the State or does the decision prescribe a certain percentage for each program? If the latter, please provide the allocation percentages for each program.

Answer. The table which follows shows how the Exxon oil overcharge funds were distributed among the States and territories.

Under the Exxon decision, States must use these funds for one or more of five programs: LIHEAP, or the Department of Energy's Low Income Weatherization Assistance Program, State Energy Conservation Program, Energy Extension Service, or "Schools and Hospitals" conservation improvement program. The court decision does not prescribe percentages to be used under each of these programs.

Because each State will choose how to divide its Exxon funds among the designated programs, we do not now know how much they will use under LIHEAP. States have told us that they used about $43 million, or a little over 20 percent, of the $200 million in "Warner Amendment funds" for LIHEAP. Exxon funds are to be used for

the same programs as Warner Amendment funds. However, we do not know whether this provides any indication as to how States will use the $2.1 billion in Exxon funds. We expect to have more information available as to how States are using the Exxon funds after we conduct our 1986 summer telephone survey.

State	Exxon Overcharge Amount
Alabama	$ 32,192,086.26
Alaska	8,272,460.20
American Samoa	371,275.67
Arizona	21,565,619.62
Arkansas	25,949,670.45
California	194,717,034.50
Colorado	22,715,884.22
Connecticut	34,900,268.97
Delaware	9,944,769.60
Dist. of Col.	4,603,515.75
Florida	98,114,523.64
Georgia	46,625,490.97
Guam	3,099,681.29
Hawaii	14,482,089.88
Idaho	8,690,739.43
Illinois	96,105,505.93
Indiana	51,631,387.53
Iowa	27,423,669.23
Kansas	23,958,453.17
Kentucky	27,438,633.15
Louisiana	51,536,267.21
Maine	15,094,373.28
Maryland	36,415,978.69
Massachusetts	70,340,939.14
Michigan	70,991,489.94
Minnesota	36,066,224.67
Mississippi	28,378,643.38
Missouri	41,516,281.45
Montana	9,584,665.67
Nebraska	15,504,944.23
Nevada	8,767,274.85
New Hampshire	9,797,536.77
New Jersey	75,432,931.59
New Mexico	13,692,730.49
New York	159,874,589.05
No. Mariana Islands	192,061.70
North Carolina	47,029,796.82
North Dakota	7,721,443.24
Ohio	79,740,285.12
Oklahoma	26,234,258.14
Oregon	20,721,692.22
Pennsylvania	96,803,642.42
Puerto Rico	20,053,948.64
Rhode Island	8,005,286.31
South Carolina	25,187,596.62
South Dakota	7,501,993.25
Tennessee	34,603,233.87
Texas	157,187,086.87
Utah	12,454,477.95
Vermont	5,005,193.65
Virgin Islands	9,951,205.30
Virginia	53,376,861.04
Washington	32,121,634.15
West Virginia	12,902,924.70
Wisconsin	36,966,568.55
Wyoming	8,874,385.60

ARKANSAS' SHARE OF ENERGY ASSISTANCE FUNDS

Question. For FY 1987, assuming the same formula applies as in current law, what would be Arkansas' share of an appropriation of $2.1 billion? Of $900 million?

Answer. LIHEAP allocations are based on each State's share of national expenditures by low-income households for heating and cooling. The LIHEAP statute requires HHS to use the most recent satisfactory data. Using the data on energy costs of low-income households available for FY 1985 and applying the current formula, Arkansas would receive approximately $15.3 million or about 0.73 percent of the funds available to States if the appropriation were $2.1 billion, with $2.358 million allocated to Federal administration. It should be noted that this estimate is based on data available for FY 1985 and may change as new data on expenditures by low income households for heating and cooling become available for calculation of FY 1987 grants.

If the appropriation falls below $1.975 billion, LIHEAP allocations are based on the percentage of funds each of the States received in FY 1984. With an appropriation of $900 million and $2.358 million allocated to Federal administration, Arkansas would receive $5,882,842 or about 0.66 percent of the funds available for the States.

1128

OFFICE OF CHILD SUPPORT ENFORCEMENT

STATEMENT OF STEVE RITCHIE, DIRECTOR

ACCOMPANIED BY:

MICHAEL DUNHAM, BUDGET OFFICER

ROBERT HARRIS, DEPUTY DIRECTOR FOR POLICY, PROGRAMS AND AUDITS

DENNIS WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTRODUCTION OF ASSOCIATES

Senator WEICKER. Our final witness this morning is Steve Ritchie of the Office of Child Support Enforcement [OCSE].

Welcome to the committee, Mr. Ritchie, and please proceed.

Mr. RITCHIE. Thank you, Mr. Chairman.

I have with me, Michael Dunham, OCSE Budget Officer, and my Deputy Director for Policy, Programs, and Audits, Bob Harris, and Dennis Williams from the Department.

Senator, with your permission, I would like to read an abbreviated statement.

Senator WEICKER. Go ahead.

Mr. RITCHIE. I will submit my full statement for the record.

As you know, established in 1975, the Child Support Enforcement Program helps to strengthen families and reduce welfare by placing the responsibility for supporting children where it belongs, with the parents. It is one of the few Government programs that helps needy families while also saving tax dollars. Most of the funds collected for families receiving aid to families with dependent children [AFDC] has gone to the Federal and State governments to offset AFDC payments.

Since fiscal year 1985, the first $50 of each current child support collection has been distributed directly to the family unit according to the requirements of the Deficit Reduction Act of 1984. As a result of this law, a smaller share of these collections are returned to the Federal and State governments, and a higher child support payment is required before families leave the AFDC rolls.

The support payments collected through the program for non-AFDC families go directly to the families to help them remain self-sufficient. The billions of dollars the Child Support Enforcement Program collects each year represent a direct benefit to children and families, as well as a direct saving to the taxpayers.

As you know, nonsupport is a serious problem for many women and children in America. More than one-half of the Nation's 14 million

children who live without their fathers are poor, and more than one-half of the women who are supported receive less than the full amount, or nothing at all. The average annual amount received in 1983 was just over $2,300. The President and the Congress addressed this problem with the passage of the Child Support Enforcement Amendments of 1984. The law we now have is beginning to work for single-parent families.

States are making progress in enacting enabling legislation and otherwise implementing the 1984 amendments. So far 47 States have passed at least some legislation in response to Public Law 98–378. Twenty of these same States have addressed all eight mandatory techniques required by Federal law. Much more remains to be done, but progress since August 1984 has been encouraging.

The fiscal year 1987 request for child support enforcement is $729 million. Included in this total is $171 million which Congress provided as an advance appropriation to fund the first quarter State and local administrative grants.

We are also requesting an advance appropriation of $187 million to fund fiscal year 1988 first quarter grants. This procedure enables States to continue program operations without interruption, and to plan in advance.

The reduction of fiscal year 1986 program funds due to Gramm-Rudman-Hollings is being largely achieved by reducing the Federal financial participation in State and local administrative expenses for program administration, as required by the law, from 70 percent to 66.65 percent, and in statewide automated data processing system design and development, from 90 percent to 85.69 percent.

Let me conclude by emphasizing the significant effort that Federal, State, and local governments are demonstrating in their endeavor to achieve an improved, more efficient, and effective program. There remains much to be done, but through the continued cooperation of all the parties, millions of American children will benefit.

As you well know, we are dealing with a complicated, difficult, and emotional issue, where there are legitimate concerns on all sides. The bottom line is what we must always remember—what is it that will give our children the best chance to be productive, creative, contributing members in our society, to reach their full potential, to be whatever they can be, to participate in the American dream?

PREPARED STATEMENT

On behalf of OCSE, we appreciate this opportunity to testify.

[The statement follows:]

STATEMENT OF STEVE RITCHIE

Mr. Chairman, members of the Subcommittee, I appreciate the opportunity to discuss the Child Support Enforcement program of the Department of Health and Human Services, and the budget we are proposing for FY 1987.

Established in 1975 as part D of title IV of the Social Security Act (the Act), the Child Support Enforcement program helps to strengthen families and reduce welfare spending by placing the responsibility for supporting children where it belongs: on the parents. It is one of the few government programs that helps needy families while also saving tax dollars. Most of the child support collected through the CSE program for families receiving Aid to Families with Dependent Children (AFDC) has gone to the Federal and State governments to offset AFDC payments. Since FY 1985 the first $50 of each current child support collection has been distributed directly to the family unit according to the requirements of the Deficit Reduction Act of 1984. As a result of this law, a smaller share of these collections are returned to the Federal and State governments and higher child support payments are required before families leave the AFDC rolls. Support payments collected through the program for non-AFDC families go directly to the family to help them remain self-sufficient. In every step of the process, the rights of the father, mother, and children are preserved. The billions of dollars the Child Support Enforcement program collects each year represent a direct benefit to children and families as well as a direct saving for taxpayers.

As most of you know, non-support is a serious problem for many women and children in this country. You have heard the sad statistics before. More than half of the Nation's 14 million children who live without their fathers are poor. More than half of the women with support orders receive less than the full child support payment due them

or nothing at all, and the average annual amount received in 1983 was $2,341.

The President and Congress addressed this problem with the passage of the Child Support Enforcement Amendments of 1984 (P.L. 98-378). The law that we now have is beginning to work hard for single-parent families. States are making significant progress in enacting enabling legislation and otherwise implementing the 1984 Amendments. So far, 47 States have passed at least some legislation in response to P.L. 98-378. And 20 of these same States have addressed all eight mandatory techniques required by the Federal Government. Much more remains to be done, but the progress since August of 1984 has been encouraging.

The FY 1987 budget request for Child Support Enforcement is $729,000,000. Included in this total is $170,750,000 which Congress provided as an advance appropriation to fund first quarter State and local administrative grants. At this time we are also requesting an advance appropriation of $187,000,000 to fund first quarter FY 1988 grants. The advance appropriation will provide funds in FY 1987 for issuing advance grants for the first quarter of FY 1988. Such a procedure enables States to continue program operations without interruption and to plan in advance.

State and Local Administrative Costs

The effectiveness and the level of collections of a State's Child Support Enforcement program determine the incentive payment the State will receive. These incentive payments, estimated at $171,000,000 for FY 1987, are reflected as an offset to child support collections in the Assistance Payments Appropriation. We are requesting $692,000,000 of

Federal funds to reimburse State and local administrative expenditures incurred in providing support enforcement services.

The Child Support Enforcement program provided a net savings to the taxpayer in FY 1985 by collecting $3.24 for every dollar spent. The Balanced Budget and Deficit Control Act (Gramm-Rudman-Hollings (P.L. 99-177)) required a sequestering of FY 1986 funds. This reduction is being largely achieved by reducing the Federal financial participation (FFP) in State and local administrative expenses of program operations, as required by the law, from 70 percent to 66.65 percent, and in statewide automated data processing (ADP) systems design and development, from 90 percent to 85.69 percent. Gramm-Rudman-Hollings maintains the incentive payment levels prescribed in the Child Support Enforcement Amendments of 1984.

Interstate Support Enforcement Project Grants

A chronic problem this nation has faced is one of enforcement of child support obligations across State lines. The Child Support Enforcement Amendments authorize demonstration projects to investigate and demonstrate innovative methods of solving this problem.

In FY 1985, 15 projects were awarded involving 37 States. Some of the projects will demonstrate or develop child support clearinghouses, paternity probability tables, data exchange systems, information standardization. It is anticipated that the initial round of FY 1986 grant awards will be completed shortly. Applications have been received from seven States to demonstrate centralized processing, interstate wage withholding, medical support enforcement, and electronic funds transfer. For FY 1987, we are requesting $15 million, the authorized level, for interstate support enforcement grants in order to continue projects already in progress, as well as, entertain new proposals.

Research and Evaluation

We are requesting $500,000 for research and evalution grants and contracts under section 1110 of the Social Security Act, the same as last year. These funds will be used to study ways to assess the progress of recent legislation and to improve distribution and accounting of collections, and for other purposes.

Federal Administrative Expenses

The FY 1987 request includes $21,883,000 in budget authority and 297 FTE's for Federal administration. This is ten below the FTE level authorized in the FY 1986 appropriation for OCSE.

During FY 1987, our staff plans to aggressively pursue a program 1) to continue implmenting the Child Support Enforcement Amendments, 2) to work in partnership with the private sector, 3) to strengthen child support enforcement across State lines, and 4) through automation, to enhance the effectiveness, efficiency, and responsiveness of State child support enforcement efforts.

Legislative Proposals

The FY 1987 budget request for the Child Support Enforcement program includes two legislative proposals. The first would reduce the State and local administrative matching rate from 70 percent to 66 percent, effective FY 1987. Under the second, the enhanced matching rate for ADP systems would be phased out over a three-year period, consistent with similar proposals in other entitlement programs.

The Federal budget proposes to build on the FY 1986 Balanced Budget Act reduction by implementing a reduction to 66 percent for administrative

expenses in FY 1987 rather than in FY 1990 as currently scheduled. While lower, the 66 percent matching rate remains generous compared to other entitlement programs. Moreover, States which improve their performance by operating more effectively will be able to qualify for increased incentive funds -- financed entirely by the Federal Government and protected under Gramm-Rudman-Hollings.

Under the ADP legislative proposal, the FY 1986 enhanced rate of 85.69 percent would be reduced to 85 percent in FY 1987, reduced to 75 percent in FY 1988 and FY 1989 consistent with the reduction proposed for this activity in the AFDC program, and in FY 1990 and thereafter matched at the 66 percent prevailing rate for State and local administrative expenses.

The Office of Child Support Enforcement also performs reimbursable work for States. This reimbursable work requires two work years and has an estimated cost of $61,000. This activity is authorized by the Parental Kidnapping Prevention Act of 1980 and involves helping to locate parents with custody of a child in violation of a court order.

Let me conclude by emphasizing the significant effort the Federal, State, and local governments are demonstrating in their endeavor to achieve an improved, efficient, and effective Child Support Enforcement program. Through the continued cooperation of all the parties million of American children will benefit. I appreciate the opportunity to testify before the committee and will answer any questions you may have. Thank you.

Biography of Steve Ritchie

Steve was born in Reidsville, North Carolina, where he was an honor student and football quarterback. He went on to become a starting halfback for the Air Force Falcons in 1962 and 1963, with his final game in the 1963 Gator Bowl.

After receiving his Bachelor of Science from the Air Force Academy in 1964, Ritchie entered pilot training at Laredo Air Force Base, Texas, and graduated first in his class.

In 1972 Steve Ritchie made aviation history when he knocked down five MIG-21's while on his second tour of duty in Southeast Asia during the Vietnam conflict. He thereby became the Air Force's first fighter Ace since the Korean War, and the only American pilot ever to shoot down five Soviet MIG-21's.

A veteran of 339 combat missions, his decorations include the Air Force Cross, Four Silver Stars, Ten Distinguished Flying Crosses and Twenty-five Air Medals.

In April 1974, Steve resigned his Air Force commission to run for the U.S. Congress from his home state of North Carolina. He is totally committed to the free market and stoutly defends the competitive system against those who would trade it for an alternative.

From November 1974 to December 1975, he was Assistant to the Chairman and Coordinator of Government Affairs for Blue Bell, Inc., (makers of Wrangler Blue Jeans).

Steve joined the Adolph Coors Company in December 1975, where he was Special Assistant to Joseph Coors for six years. In December 1981, Steve established his own speaking and consulting business, working with a variety of clients nationwide. He is past President of the Combat Pilots Association of America, a Colonel in the Air Force Reserve, and a former National Director of the Air Force Association.

His awards include: The 1972 "Mackay Trophy" for the most significant Air Force mission of the year, the 1972 "Colonel James Jabara Award for Airmanship", presented by the Air Force Academy; the 1973 VFW "Armed Forces Award" for outstanding contributions to the National Security of the United States; and in 1973, he was selected as one of the "Outstanding Young Men of America."

Steve is also a winner of two Freedoms Foundation Awards in the category of Public Address, along with recipients such as: Bill Simon, Ezra Taft Benson, and Dr. Milton Friedman. In the past 12 years, he has traveled well over a million miles throughout the United States, Canada, Europe and the Far East, presenting over 1,800 programs to more than three-quarters of a million people.

He was appointed to this current position as Director of the Office of Child Support Enforcement in January 1985, reporting to the Secretary on activities of the office, including expanded efforts to help states improve Child Support collections.

CHILD SUPPORT PAYMENTS

Senator WEICKER. In your opening statement, you stated that more than one-half of the women with support orders receive less than the full child support payment due, or nothing at all.

What improvement has there been in payment of child support since enactment of the 1984 Child Support Enforcement Amendments?

Mr. RITCHIE. We are estimating an increase, Mr. Chairman, in total collections from approximately $2.3 billion in fiscal year 1985 to about $3 billion in fiscal year 1986. Collections have been increasing every year since fiscal year 1982. It is too early to tell at this point what real long-term effects the amendments will have toward improving program performance.

We believe that as the States begin to implement the mandated procedures, proven effective in different regions throughout the country, that there will be a continued increase in collections and in efficiency.

Senator WEICKER. You say that there are 47 States that have enacted laws to implement Federal legislation?

Mr. RITCHIE. Forty-seven States have passed legislation that address at least some or all of the requirements. Twenty States have passed laws that address the eight mandatory requirements of the new Federal law. In regard to the seven States that have not passed any legislation in response to the 1984 amendments, we have to remember that they had laws on the books prior to the 1984 amendments that may or may not have fully complied with the new requirements.

All of the States are required to implement legislation by the first day of the fourth month after the first legislative session which ends on or after October 1, 1985. In some cases, it goes into 1987, depending on when the State legislatures meet.

We think that a lot of progress has been made since 47 States have already passed some legislation.

Senator WEICKER. We see sort of a reverse situation here in terms of your budget, and I don't really understand why. Why do you think you received this large increase at a time when everybody else is getting whacked pretty hard?

Mr. RITCHIE. In the program area, it is a 10-percent increase. However, in the Federal administrative area, we, along with everyone else, have sustained the 4.3-percent Gramm-Rudman-Hollings cut.

The program funding, as you know, is open ended. The States provided us estimates as to what their costs will be during the next year, including implementation of the 1984 amendments, additional automated data processing requirements and additional staff requirements. Actually, their request was for a 15-percent increase, which, after analysis, reduced to a 10-percent increase. We don't know exactly what the total outlay will be, although the estimates have been pretty accurate in the past.

Senator WEICKER. How did you come out in 1986?

Mr. RITCHIE. Over the years, it has been within about 3 percent of the estimates.

I think Gramm-Rudman-Hollings will help to improve program effectiveness. It gives the States slightly more of a burden to perform cost effectively. Some of the States are very cost effective, but some of them don't do well at all. Some are very inefficient. Gramm-Rudman-Hollings Federal match reduction will emphasize incentive payments more. The 1984 amendments provide for incentive payments to the States based on performance which was not the case in the past.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. I have further questions for response to the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

Budget Request

Question: Mr. Ritchie, what was the Office of Child Support Enforcement's original budget request to the Department? What was the Department's request to OMB?

Answer: The following chart provides OCSE's budget request to the Department and to OMB for FY 1987. The Department accepted the figures submitted by OCSE and presented those figures in its budget request to OMB.

Budget Summary
(Dollars in thousands)

	Department and OMB Requests
Program Budget	
State and Local Administration	$674,000
Automated Systems	36,000
Interstate Enforcement Grant	15,000
Research	500
Administrative Budget	23,421
Total Budget Request	$748,921

NON-PAYMENT OF COURT-ORDERED CHILD SUPPORT

Question. In your opening statement, you state that more than half of the women with support orders receive less than the full child support due them, or nothing at all. What improvement has there been in payment of child support since enactment of the 1984 Child Support Enforcement Amendments?

Answer. It is really too early to determine the results of the 1984 Amendments towards improving program performance. Thirty-four States have until sometime this fiscal year to enact the necessary legislation and begin using the mandated procedures and 18 States have even longer until sometime in FY 1987. Thus, FY 1987 and later will really be a better period for assessing impact of the 1984 Amendments.

However, annual rate increases in collections are evident since FY 1982: 9% in FY 1982; 14% in FY 1983; 17% in FY 1984; 13% in FY 1985. Slight improvement, from 40% to 43%, has been seen between 1981 and 1983 in the percentage of women below the poverty level who were eligible for child support and had an

agreement or award. Also improvement, from 72% to 76%, has been seen, between 1981 and 1983, in the percentage of women who were supposed to receive payments and those who actually received them.

Question. What is your goal or target for improving actual payment of child support?

Answer. My goals for the Child Support Enforcement program are to fully implement the Child Support Enforcement Amendments at the State level, to improve program performance financially benefiting Federal and State governments and most importantly the children, to continue the double digit increases in collections evident since FY 1983, and to maintain a better than 3 to 1 cost effective ratio. In addition, I will continue to encourage automation and reliance on the private sector for certain program operations and to build awareness and change attitudes so that payment of support will not require such a high degree of government enforcement action.

STATE NON-COMPLIANCE WITH CHILD SUPPORT LAW

Question. In your opening statement, you acknowledge that much more remains to be done to get the States to fully implement the 1984 child support enforcement legislation. What reasons do the States give for delays in implementing the practices mandated by the Federal law?

Answer. The predominant factor for the State delays in implementing the mandatory practices of the 1984 Child Support Enforcement Amendments is the need for enactment of State enabling legislation by the State legislatures. As of March 1, 1986, 20 States have legislation addressing the mandatory enforcement techniques, including States having an exemption from passing legislation because a requirement is being implemented administratively via procedures or court rules. Forty-seven States have passed legislation in response to P.L. 98-378. Seven States have not passed legislation in response to the 1984 Amendments but previously had laws addressing some of the eight mandatory requirements. In regard to all the State legislation, the provisions may be incomplete to fully comply with Federal requirements.

Question. What penalties can you impose on States for non-compliance?

Answer. If a State fails to enact the required laws and if the State does not have an approved exemption or a waiver to do a demonstration project under section 1115 of the Social Security Act, we can disallow related administrative costs and/or hold a conformity hearing which could result in the loss of all child support enforcement (IV-D) funds and possibly Aid to Families and Dependent Children (IV-A) funds. If a State has authority to carry out program requirements but fails to do so,

as determined by audit, a penalty for substantial noncompliance can be levied. The severity of the penalty is graduated ranging from a 1 percent to 5 percent reduction of a State's funding for its AFDC program. Before imposition of a penalty, a State is provided a period for corrective action and the Secretary may suspend the penalty during the corrective action period.

Question. Why not warn the States that you will consider penalties after failure to comply by specific deadlines?

Answer. We will make clear to States the consequences of failing to comply. However, we are unable to warn the States that they may be penalized if they do not comply by a specific deadline. The 1984 Amendments provided that States were required to implement the mandatory practices on October 1, 1985 unless they have been exempted, they have waiver for a demonstration project under section 1115 of the Social Security Act, or the Secretary determines that State legislation is needed. In this last instance, States must implement the practices no later than the beginning of the fourth month beginning after the first session of the State legislature which ends on or after October 1, 1985. Therefore, determining the specific deadline applicable to each State is dependent upon State legislatures actions which are beyond our control. Thirty-four States have until sometime this fiscal year to enact the necessary legislation and begin using the mandated procedures and 18 States have even longer until sometime in FY 1987, based on State legislature session calendars.

FEDERAL LOSS AND STATE GAIN

Question. Your budget documents indicate the Federal government will suffer a net loss of $331 million from the Child Support Enforcement Program, while the States will gain $339 million. The Federal government loss will be $109 million greater than in 1985, while the State surplus grew $58 million. Considering the magnitude of the Federal deficit, isn't it time the States share some more of the savings produced by the Child Support Enforcement Program with the Federal Government?

Answer. The FY 1987 legislative proposal to reduce the Federal matching rate for State administrative costs moves program funding in the direction of rewarding results more quickly than the 1984 Amendments. Under the Amendments, the revised incentive structure emphasizes cost effective performance by providing a higher percentage incentive payment as cost effectiveness increases. States are eligible for incentive payments of 6 to 10 percent of both AFDC and non-AFDC collections. The more States collect in support in an effective manner, the more money they receive. The proposal to reduce the Federal match rate does not alter the open ended funding concept for State and local administrative expenses; but does help to lessen the direct Federal deficit in child support enforcement.

The proposals also help to lessen the direct Federal deficit in child support enforcement. Additional savings realized by the Federal government, but not reflected in the CSE budget are cost avoidance to the Federal government of welfare savings related to non-AFDC enforcement and collection activities (no figure available) and Medicaid third party liability savings to the Health Care Financing Administration of approximately $60 million in FY 1987.

The total impact of the Child Support Enforcement program must be realized, for the taxpayer and for government. Total savings to the taxpayer in FY 1985 was $82 million. State savings in the same year were $305 million while the Federal deficit from the program was $223 million. The Federal share of savings is negatively impacted by the $50 disregard provision of the Deficit Reduction Act, causing a loss of approximately $98 million in FY 1985 and rising to $124 million in FY 1987. (Figures reflect actual data as reported by States for FY 1985 as opposed to figures reported in the Federal budget based on estimates.)

Question. What evidence is there that States will not cooperate as fully in carrying out child support enforcement activities if they had to share a greater portion of collections with the Federal government?

Answer. We do not know what impact changing the Federal/State apportionment of collections would have on State child support enforcement activities. Previous experience in reducing the Federal deficit in child support enforcement has been related to reducing the Federal matching of State and local administrative costs.

OCSE will monitor the actual expenditures in FY 1986 to determine whether States plan to reduce their level of services in the out years should Gramm-Rudman-Hollings provisions again be called into effect.

Question. When do you expect to see this program become more cost effective for the Federal government?

Answer. Because of the CSE Amendments of 1984, States will continue in the short term to invest a significant amount of their resources into operations that will only fully realize savings to the CSE program and the Federal government after FY 1987. These resources include new staff, cooperative agreements with State and local agencies, ADP equipment, etc. This has the effect of "front loading" costs on the program and masking any increase in cost effectiveness through FY 1987.

FY 1987 legislative proposals move program funding even more in the direction of rewarding results, not just funds spent on administration. They also help to lessen the direct Federal deficit in child support enforcement.

INTERSTATE PROJECTS

Question. You are requesting $15 million for interstate support enforcement grants, an increase of $3.5 million over the FY 1986 level. Provide for the record a list of the projects currently being funded, as well as your plans for new projects in FY 1987.

Answer. Plans for projects in the interstate area include funding additional States for existing clearinghouse projects and funding new multi-state clearinghouse efforts, in order to reach toward a national system to track interstate cases. It is also anticipated that some additional efforts will be funded to improve the processing of cases based upon data gathered from existing tracking systems and State interstate management studies. Finally, a number of State initiated efforts will be funded to improve interstate processing and child support enforcement for interstate cases.

A list of projects currently funded follows:

Interstate Grants

PROJECT NUMBER	TITLE	GRANTEE	PROJECT GOALS	STATUS
19-P-10001-10-01	Western Interstate Clearinghouse for CSE.	State of Alaska Department of Revenue CSE Division	To establish a common sef of data elements for processing interstate cases within Region X and to set up an automated system for case tracking and monitoring.	In progress. Project period June 1, 1985 to May 31, 1986.
19-P-10002-4-01	Alabama URESA Paternity Establishment Project	Alabama State Department of Pensions and Security Bureau of Child Support.	To improve the establishment of paternity in URESA cases through the use of standardized forms, procedures, laboratory testing, and videotaping courtroom testimony.	In progress. Project period is June 1, 1985 to May 31, 1986.
19-P-10003-5-01	Midwest Support Enforcement Clearinghouse	Illinois Dept. of Public Aid	Over the course of 3 years, the project will analyze impediments to interstate enforcement, create and test a computerized clearinghouse for locating absent parents, and create and test a computerized Case Expediting and Tracking System.	In progress. Project period is June 1, 1985 to May 31, 1986.
19-P-10005-3-01	Interstate Analysis and Improvement Demonstration	Maryland Dept. of Human Resources CSE Administration	To analyze current interstate operations and problems, and then to develop and test improvements.	In progress. Project period is June 1, 1985 to May 31, 1986.

PROJECT NUMBER	TITLE	GRANTEE	PROJECT GOALS	STATUS
19-P-10006-7-01	Region VII Interstate Enforcement System	Iowa Dept. of Human Services	Develop and demonstrate an automated system on the interstate location of absent parents and in the interstate implementation of various enforcement remedies. Also, to develop a process by which Region VII states can enforce child support obligations of absent parents located in states outside the region.	In progress. Project period July 1, 1985 to June 30, 1986.
19-P-10007-1-01	New England Interstate Project	Massachusetts Dept. of Public Welfare.	Develop regional interstate directory, standardized procedures and forms, processing time standards, implement interstate legislation and develop a model legislative package, study feasibility of an automated interstate network.	In progress. Project period is June 1, 1985 to May 31, 1986.
19-P-10000-3-01	Improving Interstate Case Processing in the District of Columbia	Bureau of Paternity and Child Support Enforcement, Dept. of Human Services, District of Columbia	To do a needs assessment of interstate case processing in the District of Columbia and to test the feasibility and cost effectiveness of a central unit or clearinghouse for facilitating and coordinating interstate activities.	In progress. Project period is October 1, 1985 to September 30, 1986.
19-P-10009-1-01	Interstate Analysis and Improvement Demonstration	Connecticut Dept. of Human Resources	To analyze current interstate operations and problems, and then to develop and test improvements.	In progress. Project period is October 1, 1985 to September 30, 1986.

PROJECT NUMBER	TITLE	GRANTEE	PROJECT GOALS	STATUS
19-P-10010-4-01	Metropolitan Interstate Child Support Enforcement: Research and Experimental Demonstration Project	Kentucky Cabinet for Human Resources Division of CSE	To conduct basic research regarding the problem of child support enforcement in the Cincinnati, Ohio/Covington-and Newport, Kentucky metropolitan area. The project is designed to apply the findings from that research to demonstrate the effectiveness of integrating a private sector style system to the collection of URESA cases.	In progress. Project period is October 1, 1985 to September 30, 1986.
19-P-10012-2-01	Human Lymphocyte Antigen Gene Frequencies of Puerto Ricans and U.S. Virgin Islanders	Puerto Rico Dept. of Social Services, Child Support Program	To identify genetic characteristics of the people of Puerto Rico and the U.S. Virgin Islands. This will enhance the usefulness of HLA techniques in paternity suits.	In progress. Project period is October 1, 1985 to September 30, 1986.
19-P-10014-5-01	Michigan Interstate Child Support Enforcement Project	Michigan Dept. of Social Services	To conduct a comprehensive assessment of interstate case processing in Michigan and its high interchange jurisdictions. The assessment will lead to the identification of several innovations in staffing, training, and interstate coordination that are designed to enhance the efficient processing of interstate child support cases and maximize collections.	In progress. Project period is October 1, 1985 to September 30, 1986.

PROJECT NUMBER	TITLE	GRANTEE	PROJECT GOALS	STATUS
19-P-10015-3-01	Delaware Interstate Child Support Demonstration Project	Delaware Dept. of Social Services	To evaluate the effectiveness, costs and benefits of expedited judicial processes, expanded use of non-(R)URESA enforcement remedies, staffing innovations, establishing formal linkages with high case interchange states, computer data tape exchanges of location and financial information and study the feasibility of an automated system for case study, tracking and monitoring.	In progress. Project period is October 1, 1985 to September 30, 1986.
19-P-10018-4-01	Electronic Parent Locator Network (EPLN)	South Carolina Department of Social Services, CSE Division	To electronically link the parent locator data bases of each of the eight states in Region IV, and provide each state with electronic access to all data bases thus limited for direct search capability.	In progress Project period is October 1, 1985 to September 30, 1986.
19-P-10019-8-01	Colorado Child Support Enforcement Interstate Network	Colorado Dept. of Social Services	To develop, pilot, evaluate, modify, and implement statewide an effective and efficient interstate process for child support enforcement.	In progress. Project period is October 1, 1985 to September 30, 1986.
19-P-10020-2-01	Title IV-D Intra-Corporate Data Exchange	New Jersey Dept. of Human Services	Using the Standardized Computer Format developed by the President's Council on Integrity and Efficiency, data tapes will be exchanged for locating absent parents and providing current information on wages, unemployment insurance benefits, and state income tax refunds which are available for child support.	In progress. Project period is October 1, 1985 to September 30, 1986.

ADMINISTRATIVE COSTS OF CHILD SUPPORT ENFORCEMENT

Question. You are requesting $692,000,000 for State and local administrative expenses in providing child support enforcement services. How do you determine what staff is needed at the State and local level to effectively administer the child support enforcement program?

Answer. The Federal government regulates that the State child support agency have an organizational structure and sufficient staff to fulfill the required State level functions. In addition, we require that there is an organizational structure and sufficient staff, at the State and local level, to provide for the administration or supervision of the varied support enforcement functions.

Question. Have any States indicated they are hampered in carrying out the law due to lack of Federal appropriations for staff or automated data processing systems?

Answer. No. Federal matching of State and local administrative costs for child support enforcement is open ended. The Federal financial participation rate currently is 66.65 percent. We have proposed to continue the 66 percent Federal match in FY 1987 to further encourage efficiency and effectiveness. In FY 1985, States reported over 23,000 full-time equivalent employees in program administration, including district attorneys, clerks of the courts, and others under cooperative agreement.

To date, 33 States are involved in some phase of development for statewide, comprehensive ADP system at the enhanced 90 percent funding rate. After several years of preliminary planning on the part of States, FY 1986 and FY 1987 represent years in which States will experience the largest increase in expenditures to implement those plans. Several States have achieved short-term payback and expect long-term benefits measurable in dollars. Immediate benefits have accrued as a result of system planning activities. States have evaluated their program organizational structures, case processing and financial management procedures revealing some inefficient and ineffective procedures and taken corrective action. Planning for automated systems has improved communications and program processing with steering committees, task forces, user groups, etc., thus resulting in a more cohesive and uniform program.

Question. Exactly where do you plan to cut Federal staff by 10 full-time equivalent positions in FY 1987?

Answer. As of March 15, 1986, OCSE had used 142 cumulative full-time equivalency work years with an end-of-year projection of 302. We anticipated reaching our goal of 297 FTEs for FY 1987 through normal attrition.

Questions Submitted by Senator William Proxmire

STATE & LOCAL ADMINISTRATIVE COSTS

Senator Proxmire. Mr. Ritchie, I continue to be concerned over discrepancies between the amount the Federal government is giving the states for administrative costs and the Federal share of collections. Let me illustrate what I mean by referring to New York and Wisconsin. In 1985 the Federal government paid New York $74,011,000 for administrative costs and received $19,456,000 as its share of collections. By contrast, Uncle Sam paid Wisconsin $13,458,000 for administration and received $18,434,000, almost as much as from New York, as its share of collections. This continues to be more or less the case in 1986 and 1987 according to your projections, despite changes in the law. What can be done to correct this situation?

Mr. Ritchie. States have varied significantly in their performance due to the administrative structure imposed (e.g. county vs. state operated), the degree of automation of the program, implementation of cost effective collection techniques, and the priority States have given CSE in terms of resource allocation.

The State of Wisconsin operates a very effective child support program. Their ratio of total collections to total expenditures is well above the national average. We wish more States were as cost effective as Wisconsin in enforcing child support.

This situation can be corrected in part through implementation of our FY 1987 legislative proposals, which would move program funding towards rewarding results and not just pay for whatever is spent on administering this program. Under our proposal, States matching rates would remain at 66 percent in FY 1987 and beyond, but States would be eligible for incentive payments from six to ten percent of AFDC and non-AFDC collections. The more States collect in support in an effective manner, the more money they receive. This proposal doesn't alter the open ended funding of this program, but does help to lessen the direct Federal deficit in Child Support Enforcement.

We are striving to improve cost effectiveness through implementation of the 1984 Amendments which offer stimuli for an improved program by relating the incentive structure and reduced Federal matching to program performance. The mandatory State practices enhance States' abilities to efficiently and effectively collect child support. We are also encouraging automation and reliance on the private sector for certain program operations and building awareness and changing attitudes so that payment of support will not require as high a degree of governmental enforcement action.

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PATERNITY PROBABILITY TABLES

Senator Proxmire. Mr. Ritchie your prepared statement, in discussing Interstate Support Enforcement Project grants, refers to a paternity probability table project. Can you tell us what that project is all about and how much it will cost?

Mr. Ritchie. The Human Lymphocyte Antigen (HLA) Gene Frequencies of Puerto Ricans and U.S. Virgin Islanders project will identify genetic characteristics of the people of Puerto Rico and the U.S. Virgin Islands. This will enhance the usefulness of HLA techniques in paternity suits.

This proposal is directed at the development of more appropriate HLA A and B gene frequencies and HLA Haplotype frequencies tables for the two ethnic groups, Puerto Ricans and U.S. Virgin Islanders. Having genetically correct gene frequency tables for these two populations would be extremely beneficial in increasing the use of parentage blood testing in Puerto Rico, the U.S. Virgin Islands, as well as in cases occurring in the Continental U.S.A. involving individuals of these ethnic groups. Correct gene frequency tables for these two ethnic groups are also necessary for the appropriate resolution of paternity cases involving mixed ethnic backgrounds of the adults involved.

Synopsis of Puerto Rico Interstate Project

1. Participants: Lead State - Puerto Rico in conjunction with the U.S. Virgin Islands.

2. Money: 1 year $353,984 ($337,128 Federal).

3. Project Goals:

   a.) HLA typing of 800 Puerto Ricans and U.S. Virgin Islanders, in order to accumulate gene frequencies of the HLA gene in Puerto Ricans and U.S. Virgin Islanders. Gene frequencies in these two groups are thought to be different from the observed gene frequencies of European and North American Caucasian and Negroes.

   b.) Identification of Unique Serological Reagents for Puerto Ricans and U.S. Virgin Islanders. Blood sera will be obtained from pregnant Puerto Rican and U.S. Virgin Islander women in order to identify new and unique HLA serological reagents that will identify additional HLA A and B Gene products.

c.) Construction of Puerto Rican and U.S. Virgin Islander Gene Frequency tables. There is an internationally agreed upon manner to construct gene frequency tables. These genetic and statistical methods have not been applied because of the lack of the HLA typing data of these two ethnic groups. By generating the data, as outlined above, the necessary analyses can be done to derive the tables.

GRADE CREEP

Senator Proxmire. Mr. Ritchie, I notice that your original average GS grade estimate for fiscal year 1986 as contained in last year's justifications was 10.39. Your current justifications indicate that the average GS grade for 1986 has now creeped up to 11.0. Can you tell us what factors contributed to this increase of approximately half a grade above your original estimate?

Mr. Ritchie. The increase is the result of greater attrition among lower graded staff than among professional staff. The Office of Child Support Enforcement consists of higher-graded oversight and technical advisory functions, with the operational activities performed by the States. Consequently, the technical expertise required for the implementation and interpretation of the legislation and regulations requires substantial GS/GM 11-15 level activities. In addition, the implementation of the Child Support Enforcement Amendments of 1984 requires staff with extensive computer and analytical skills. Our current grade average is 10.39.

SUBCOMMITTEE RECESS

Senator WEICKER. We will stand in recess until 9:30 tomorrow morning, and at that time, we will hear testimony from Human Development Services, the Office of Community Services, departmental management, salaries and expenses, and policy research.

Thank you very much.

[Whereupon, at 10:52 a.m., Tuesday, March 18, the subcommittee was recessed, to reconvene at 9:30 a.m., Wednesday, March 19.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1987

WEDNESDAY, MARCH 19, 1986

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:30 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker, Andrews, Specter, Burdick, and Harkin.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF HUMAN DEVELOPMENT SERVICES

STATEMENT OF HON. DORCAS R. HARDY, ASSISTANT SECRETARY FOR HUMAN DEVELOPMENT SERVICES

ACCOMPANIED BY:

NORMAN GOLDSTEIN, DIRECTOR, OFFICE OF MANAGEMENT SERVICES
DENNIS P. WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

OPENING STATEMENT

Senator WEICKER. The subcommittee will come to order.

Today we will hear testimony concerning appropriations under the Office of Human Development Services and the Office of Community Services, followed by testimony on departmental management activities.

We will begin with Dorcas Hardy, Assistant Secretary for Human Development Services, and then we will hear from Jerrold Speers, Director of the Office of Community Services.

Senator Harkin will conduct, in the main, this hearing this morning because I have a meeting of the Health and Human Services authorizing committee upstairs.

It is a pleasure, Dorcas, to have you here. Why don't you introduce those that are accompanying you. Your statement in its entirety will be placed in the record. Proceed in any way you wish. Also, let me provide congratulations on your new position.

INTRODUCTION OF ASSOCIATE

Ms. HARDY. Thank you, Mr. Chairman.

I am accompanied by Norman Goldstein, Director of the Office of Management Services. I have a very short and informal statement.

Our budget request for 1987 is approximately $5.5 billion and all the money will be targeted toward the goal of promoting economic and social self-sufficiency among all of our vulnerable populations.

As a result of the Deficit Reduction Act, all of our programs have been reduced in 1986, but we believe that we can operate with these reductions with minimum impact on direct service levels.

Our 1987 budget restores the funding levels to pre-Gramm-Rudman-Hollings levels for our services programs. There are some reduced levels of support requested for discretionary programs which do not provide direct services.

PREPARED STATEMENT

Since we saw you last year, we think we have had quite a successful year in a lot of our initiatives, which I will be glad to go into in further detail, but I will turn to you and ask if you have any further questions.

[The statement follows:]

STATEMENT OF HON. DORCAS R. HARDY

I am pleased to appear before you today to discuss the fiscal year 1987 budget request for programs administered by the Office of Human Development Services and the requests for rescissions for fiscal year 1986.

For 1987, a total of $5,496,215,000 is requested to support a variety of social programs which serve children and youth and their families, the elderly, those who are developmentally disabled, and Native Americans. Of the total requested, $2,700,000,000 is requested for the Social Services Block Grant appropriation; $1,978,378,000 is requested for the Human Development Services appropriation; and $817,837,000 is requested for the Family Social Services appropriation. No funds are requested for the Work Incentive Program (WIN). Amounts requested for most Human Development Services programs are the levels requested by the President for fiscal year 1986, and reflect restoration of the Gramm-Rudman-Hollings reductions in most cases.

With the exception of the Work Incentive Program, service levels for all programs supported in fiscal year 1986 will be maintained or increased to the extent possible.

A level of $2,700,000,000 is requested for the Social Services Block Grant to continue support for a variety of social services in each State. The amount requested represents the full authorization for this program in fiscal year 1987. Services which a State may choose to provide may include, but are not limited to: child and adult day care services, protective services, foster care, transportation, training, information and referral, counseling, delivery of meals, and health support.

A level of $1,978,378,000 is requested for the Human Development Services appropriation. This appropriation includes programs for children and youth and their families, the elderly, those who are developmentally disabled, and Native Americans.

For the Head Start program, $1,075,059,000 is requested to support comprehensive child development services to 448,250 preschool children and their families, the same number served in 1985 and 1986.

For Family Crisis and Protective Services, $30,500,000 is requested. This new program, for which legislation will be proposed, will consolidate Child Abuse and Neglect and Family Violence activities to provide greater flexibility to States in meeting the specific needs of their respective populations. The proposal will retain many of the important reporting and protective requirements currently in the law.

For Runaway and Homeless youth programs, $23,250,000 is requested to support 285 centers expected to serve 86,000 youth and their families.

For the Administration on Aging, a level of $689,100,000 is requested. The request will provide a wide range of social and nutrition services to approximately 9 million elderly persons. Approximately 222 million meals will be served to over three million older persons.

For Developmental Disabilities programs a level of $73,000,000 is requested. The program will continue to support State systems which coordinate, monitor, and evaluate and promote services and opportunities provided to the developmentally disabled; to provide for systems of protection and advocacy of individual rights of persons who are

developmentally disabled; and to provide support for University Affiliated Facilities.

For Native American programs, $27,300,000 is requested to promote social and economic self-sufficiency for American Indians, Alaska Natives and Native Hawaiians.

An amount of $60,169,000 is requested for Human Development Services Program Direction. These funds will provide effective and efficient management of all programs administered by the Office of Human Development Services.

A level of $817,837,000 is requested for the Family Social Services appropriation. The Administration has proposed legislative changes in the Foster Care program that will improve State incentives to effect early reunification of children with their families or provide for other permanent placement for children. Funds requested will continue to provide assistance to States to strengthen the family unit, to reunify children with their families, or, where this is not possible, to find suitable adoptive homes for them. These funds will support the Child Welfare Services and Training programs, and the Foster Care and Adoption Assistance programs, Child Welfare Research and Demonstration, Adoption Opportunities, and Social Services Research.

The Work Incentive Program is proposed for phase-out in 1987. Instead, in conjunction with the Department's Work Opportunity initiative, AFDC applicants and recipients will be required to participate in job search and other employment-related activities as a condition of AFDC eligibility.

We are also proposing rescissions to reduce the 1986 amounts available for most programs to the levels proposed in the President's Fiscal Year 1986 budget.

For Human Development Services, rescissions in the amount of $29,980,000 are proposed. For the most part, these rescissions are against discretionary programs which do not provide direct services. We believe that the amounts available after rescinding would be sufficient to support high quality research, demonstration, and training activities.

For Family Social Services, rescissions in the amount of $6,157,000 are proposed. These rescissions reduce support for discretionary programs and no loss of services would result.

For the Work Incentive Program, fourth quarter funding totaling $45,884,000 is proposed for rescission consistent with the Administration policy to phase out the WIN program completely in FY 1987.

Thank you, Mr. Chairman. My Colleagues and I will be happy to answer any questions you and the Committee may have.

BIOGRAPHY OF HON. DORCAS R. HARDY

POSITION	:	Assistant Secretary, Office of Human Development Services
BIRTHPLACE AND DATE	:	Newark, New Jersey, July 18, 1946
EDUCATION	:	B.A., Connecticut College, New London, Connecticut, 1968
	:	M.B.A., Pepperdine University, Los Angeles, California, 1976
	:	Executive Program in Health Policy and Financial Management, Harvard University, December, 1978
EXPERIENCE		
Present	:	Assistant Secretary, Office of Human Development Services

1974-1981	:	Associate Director, Center for Health Services Research, University of Southern California School of Medicine, Los Angeles, California
1974	:	Health Consultant, Urban Management Consultants, San Francisco, California
1973-1974	:	Assistant Secretary for Health, California Health and Welfare Agency, Sacramento, California
1971-1973	:	Executive Director of Health Services Industry Committee, Cost of Living Council, Washington, D.C.
1970-1971	:	Special Assistant to National Chairman and Director, White House Conference on Children and Youth, Washington, D.C.
1970	:	Legislative Research Assistant, Senator Clifford P. Case, Washington, D.C.

BUDGET REQUEST TO DEPARTMENT

Senator WEICKER. Fine. I will now turn the chair over to Senator Harkin.

Senator HARKIN [presiding]. Secretary Hardy, let me also welcome you to the subcommittee. I appreciate the opportunity to chair it during your testimony.

Ms. HARDY. Thank you.

Senator HARKIN. We do have a series of questions that Senator Weicker wanted me to propound to you. The first has to do with the budget itself.

Secretary Hardy, what was the original budget request from the Office of Human Development Services to the Department?

Ms. HARDY. Senator, we look at the overall budget request. We can provide the specific numbers, but basically as a departmental exercise that we go through, with a lot of give and take, the proposals that we made originally are very close to the final proposals that are in the President's budget that we are talking about this morning.

Senator HARKIN. But you have no numbers for me?

Mr. GOLDSTEIN. The total amounts to about $5.5 billion.

Senator HARKIN. You must have the exact number. When you put in a request, you have the exact numbers.

Mr. GOLDSTEIN. It is $5,571,428,000.

Senator HARKIN. That is your original request; right?

Mr. GOLDSTEIN. Yes.

BUDGET REQUEST TO OMB

Senator HARKIN. What was the Department's request to OMB?

Mr. GOLDSTEIN. It was $5,599,361,000.

Senator HARKIN. So the request from the Department was more than your request.

Ms. HARDY. Correct.

Senator HARKIN. What was the difference there?

Mr. GOLDSTEIN. It is a $28 million difference.

Ms. HARDY. As I said, there is a lot of give and take. We proposed some decreases which the Department did not agree with, and it raised our request in other cases.

Senator HARKIN. What were the decreases that you suggested?

Ms. HARDY. The decreases are also part of the current rescission package. We proposed decreases in the Child Abuse Challenge Grants and Dependent Care Programs. We proposed an increase in the Head Start Program. The President's budget has some of those increases, and some of those decreases.

Senator HARKIN. Your decreases total more than your increases.

Ms. HARDY. Correct. I always believe, Senator, that we can do more with less money, so I generally propose a lower budget.

Senator HARKIN. You can do more with less money.

Ms. HARDY. Yes.

Senator HARKIN. Is this just a general rule of life, or what?

Ms. HARDY. No; it is the rule in HDS.

Senator HARKIN. It sounds like something you might read out of a Golden Book, or something.

Ms. HARDY. Well, we think that we have done more with less money in HDS over the past 5 years.

RESCISSION PROPOSALS

Senator HARKIN. You have proposed a number of rescissions of fiscal year 1986 appropriations for programs serving children, youth, the elderly, welfare recipients, and the developmentally disabled.

Can you assure us that steps will be taken to promptly release these funds when the rescissions expire on April 15?

Ms. HARDY. If the Congress does not go along with the proposed rescissions, yes, we will go ahead and expend those dollars in this fiscal year.

Senator HARKIN. As I understand, the rescissions expire on April 15. In other words, we don't have to take any action.

Ms. HARDY. Correct, if you do not take any action, we will release those funds in a timely fashion.

Senator HARKIN. What does that mean?

Ms. HARDY. Immediately, to me, would mean within the next 24 hours.

Senator HARKIN. No; but you would start right away.

Ms. HARDY. Yes, sir.

Senator HARKIN. From the date the rescissions expire, April 15, how long do you estimate it will take to disburse the appropriated funds as required by law?

Ms. HARDY. All of those funds will be obligated by the end of the fiscal year, by September 30, 1986. Some funds can go out this spring. Some of the other moneys are moneys for which you apply, you compete as a grantee, as an applicant. That process is ongoing, and some of that will have to be started. But all funds will be obligated by the end of the fiscal year according to the wish of Congress.

CATEGORICAL FUNDING RECOMMENDATIONS

Senator HARKIN. You are requesting zero appropriations for several programs aimed at child abuse and family violence prevention, evidently based on the assumption that Congress will enact block grant legislation that you have not yet even submitted.

I would like to know your funding recommendations for the following programs as they currently exist, since we obviously appropriate on the basis of current law. Family violence prevention, can you tell me what your funding recommendation is for that?

Ms. HARDY. For all of these, Senator, if the formula grant just proposed by the administration is not accepted by the Congress, we need to have further discussion in the Department, but it would probably be funding level with the 1985 levels as proposed.

Senator HARKIN. That is the family violence prevention.
Ms. HARDY. Family violence, child abuse.

FAMILY VIOLENCE

Senator HARKIN. I want to go through each one. What is your figure for family violence prevention?
Ms. HARDY. It was $6 million in 1985.
Senator HARKIN. The fiscal year 1986 level is $8.5 million.
Ms. HARDY. That was a combination, if I remember, Senator, of carryover moneys from 1985 and the 1986 appropriation.
Senator HARKIN. Are you saying that the $8.5 million was a combination of 1986 and 1985?
Mr. GOLDSTEIN. The 1985 money, the $6 million was appropriated at the very end of the 1985 fiscal year. The Congress authorized that money with a 2-year availability. In 1986, since we had the 2-year availability in 1985, they only authorized $2.5 million. So the combination of the 1985 and the 1986 appropriations is $8.5 million.
Senator HARKIN. Let me get this straight. For 2 years, 1985 and 1986, you are telling me the level was really $4 million a year. Is that what you are saying?
Mr. GOLDSTEIN. Your question was—what was the family violence funding in 1985. The funding in 1985 was $6 million.
Senator HARKIN. The funding in 1986 was what?
Mr. GOLDSTEIN. It was $2.5 million, with some availability from 1985.
Senator HARKIN. So for the 2 years, if you average out the 2 years, it was $4,250,000; right?
Mr. GOLDSTEIN. That would be the average.
Ms. HARDY. That is correct. It is a new program.
Senator HARKIN. It was authorized at $11 million; right?
Ms. HARDY. Yes; I believe so. It was authorized higher than it was appropriated.
Senator HARKIN. A lot higher, $11 million.
Now you are saying that your recommendation for this year is to go to $6 million, the 1985 level?

FAMILY CRISIS PROPOSAL

Ms. HARDY. Our recommendation for this year is a Formula Grant Program which combines all of these so that we don't have such a categorical approach. We believe that we can serve, and the States can serve these populations in a lot better fashion if they have the flexibility under a formula grant. So I don't have a specific number for you.
Senator HARKIN. The ones that you are talking about are family violence prevention, child abuse State grants, child abuse discretionary grants, and challenge grants; right?
Ms. HARDY. Yes, sir.
Senator HARKIN. Those are the ones that you are talking about.
Ms. HARDY. That is what we have proposed.

Senator HARKIN. You have proposed putting them all together under one formula grant.

Ms. HARDY. Correct.

Senator HARKIN. What are you requesting for all of those?

Mr. GOLDSTEIN. We are requesting $30.5 million.

Senator HARKIN. How much was appropriated by the Congress last year?

I will tell you what it was, it was $39.5 million.

Ms. HARDY. I am not sure that I agree with that.

Senator HARKIN. You don't agree with that? What do you have?

Ms. HARDY. It depends on how you add, Senator. If you add the things that you have added in, that is approximately $39 million. I had made some other assumptions, and we added it differently. I get about $30 million.

Senator HARKIN. We will discuss that in a minute.

Senator Andrews.

ELDERLY ABUSE

Senator ANDREWS. Thank you, Mr. Chairman.

The Senator asked a couple of questions about specific child abuse programs, and others. Let me narrow it down even more.

The Elderly Abuse Program that we directed you to start five pilot projects in five States, and provided $500,000. What steps have been undertaken by your office to comply with this report language?

Ms. HARDY. Senator, we are in the process of doing that. That language came out late last year.

Senator ANDREWS. It came out when your appropriation came out, sure.

Ms. HARDY. Correct. We are in the process of competing those dollars through our coordinated discretionary program.

Senator ANDREWS. What States have applied for funding?

Mr. GOLDSTEIN. We would have to get back to you. As I understand it, there are 21 applications in that general area.

Senator ANDREWS. That is what the Secretary said, Mr. Goldstein. I assumed that since the Secretary was asked by this committee, said that there were 20, that when you came in, you would fill in the gap.

Ms. HARDY. We haven't finished the competitive process.

Senator ANDREWS. Fine, but the $500,000 is being made available, are you saying that?

Ms. HARDY. Yes; it is in the works.

Senator ANDREWS. So you are going to set up five demonstration projects; is this true?

Mr. GOLDSTEIN. We have every intention to do that, yes.

Senator ANDREWS. When will you release this money?

Mr. GOLDSTEIN. The decisions on the whole process are expected to be completed shortly. Our outside timeframe is the end of April.

FUNDING ELDERLY ABUSE PROJECTS

Senator ANDREWS. So by the end of April, you will announce, and you can give this committee the information as to the five States that have been picked for the Elderly Abuse Program.

Mr. GOLDSTEIN. In that general area, yes.

Senator ANDREWS. You will then disburse the $500,000 average per State for this elderly abuse situation?

Mr. GOLDSTEIN. Yes.

Senator ANDREWS. This will be done by the end of April.

Mr. GOLDSTEIN. You have to understand the process. I said the decisions in terms of the competitive process would be completed by the end of April. After those decisions are made, there is a further analysis that is done in the area of grants management, and also possibly in terms of the program offices, in finalizing the applicant's budget and specific scopes of work, and that could take another couple of weeks. The whole process is expected to be completed, hopefully, by the end of the third quarter.

Senator ANDREWS. Do you mean that it is going to take until the end of June, but you are telling the committee that the $500,000 will be disbursed by the end of June?

Mr. GOLDSTEIN. Yes; we have every hope to meet that timeframe. We are dealing with 2,200 applications that came in as a result of the CDP process.

Senator ANDREWS. How many applications?

Ms. HARDY. 2,200 for a broad variety of issues, including elderly abuse.

Senator ANDREWS. I am talking specifically about the elderly abuse. I am talking about $500,000 specifically for elderly abuse that you are going to disburse, as you have said now.

The reason the committee was concerned is because, in part, your budget justification states that it would not be possible to guarantee support for specific kinds of projects or the level of support.

Now you are telling the committee that you are going to fund the elderly abuse at the $500,000 level that you were told to do.

Ms. HARDY. If we have acceptable, quality, highly ranked, good projects, we will spend the money in that area.

Senator ANDREWS. OK.

Ms. HARDY. We have also recently put a notice in the Federal Register for family violence, and in there there is discussion of spending money on elder abuse. So we are looking at that within our whole context of family violence within HDS.

QUALITY OF PROJECT PROPOSALS

Senator ANDREWS. That is right, and we don't want it melded in. You are legally bound to spend the $500,000 for elderly abuse, there is no question about that in your mind, is there?

Ms. HARDY. If we have good projects.

Senator ANDREWS. When Secretary Bowen said that you had 20 applications, I would assume, wouldn't you, Senator Harkin, that out of 20 applications, you can find five that are suitable?

I would assume, when you are talking about 2,200 applications, when the Secretary says 20, he is referring to 20 that are pretty quality applications.

Ms. HARDY. We don't know that yet, but we are hopeful.

Senator ANDREWS. Do you mean that you haven't looked at them?

Ms. HARDY. I have not looked at them, no.

Senator ANDREWS. Who has?

Ms. HARDY. Staff is looking at them. They are being competed through panels, and outside reviewers, but they have not yet been decided.

Senator ANDREWS. How much of the $500,000 might get chewed up in this review process, and all of this?

Ms. HARDY. None.

WHEN PROJECTS WILL BE FUNDED

Senator ANDREWS. How much longer, since the Secretary was here 3 weeks ago, and I am using this as a microcosm in time of what you were asking in a number of other programs, to find out how they follow through. How much longer is this process going to take?

You say, until the end of April, and then you will have a hand on it, and then it will take until the end of June to award them. Is that a timetable that we can expect, not only in the elderly abuse, but in these other areas that Senator Harkin was talking about?

Ms. HARDY. Most of our funding does go out in the third and fourth quarters. As soon as those decisions are made, we can move that whole group to the front of the grant cutting and funding mechanism, and certainly try very hard to get that out far before the end of June.

There are a great many process pieces in HDS. We cut thousands of grants.

Senator ANDREWS. But you are telling us that you will comply with this report language.

Ms. HARDY. Assuming that we have quality, competent, good applications, yes, sir.

Senator ANDREWS. You will give a report back to this subcommittee at the end of April as to the quality of these applications.

Ms. HARDY. If you would like that at the end of April, yes, sir.

Senator ANDREWS. You said that this is when you will have them evaluated, and we would like it because we would like to track just what you are doing.

At the end of June, you will give us, of course, the report as to who we disbursed the funds to. If you can give us that report at the end of April, we will see how we are doing.

We appreciate your assurance of full funding for this program, and I appreciate the time.

CONSOLIDATED PROGRAM REQUEST

Senator HARKIN. Thank you, Senator.

Secretary Hardy, could we return to the consolidated programs that you are talking about. Again, I just want to clear this up, and I want to see if I am right on this.

We appropriated $39.5 million, we, in the Congress, appropriated this money in fiscal year 1986 for these four programs. Is that correct?

Mr. GOLDSTEIN. That is correct, but I believe, in calculating your $39 million, you included the money that was available on a 2-year basis.

Senator HARKIN. Absolutely.

Mr. GOLDSTEIN. Fine.

Senator HARKIN. What you are saying, though, is that you are only going to spend $30.5 million.

Mr. GOLDSTEIN. What you have is a set of four rather narrowly defined categorical programs all within the area of child abuse and family violence.

Senator HARKIN. Yes.

Mr. GOLDSTEIN. Each of those programs requires a lot of overhead, regulation, a lot of impact in terms of administration, both from the State's point of view, as well as the Federal point of view. Our proposal is predicated on the basis that certain efficiencies will occur and the States will have greater flexibility in administering this program, as it relates to the whole area of family violence and child abuse. They will be able to more effectively apply the resources provided to the particular problem that we are concerned with.

Ms. HARDY. Senator, we are in the process of spending approximately $7.1 million for State grants in the area of family violence.

Senator HARKIN. Since October 1.

Ms. HARDY. Correct. Each of the programs proposed for consolidation took a 4.3-percent reduction. So there isn't the total $39 million. We also have asked for a rescission of the Challenge Grant Program. It may be available on April 16, but it is not in my addition at the moment.

I assume that what you are asking us is whether there is a reduction in terms of the formula grant. The way we look at it, the amount requested for 1987 is slightly higher than the amount proposed for 1986, assuming rescissions are enacted.

We also would retain a portion with the National Center for Child Abuse and Neglect for discretionary dollars. We can supply the figures for the record, if you would prefer.

CHALLENGE GRANTS

Senator HARKIN. Why do you propose to rescind the challenge grants?

Ms. HARDY. The challenge grants were proposed by the Congress to address an area where I think the States have gone far beyond, and the dollars are not needed.

Senator HARKIN. Tell me about the challenge grants.

Ms. HARDY. Thirty States have trust funds. Basically, the challenge grants reimburse States that have trust funds to promote spending on child abuse and neglect prevention. Generally this spending is more for demonstration, research, and local-based projects, rather than direct service.

Thirty States have challenge grants, have some kind of trust funds, and they have done this very well without us. We have been very pushy with the States to encourage them to do this. Many of the States have checkoffs on tax returns, and have other ways that they are using to build up their trust funds. We feel that a $5 million program is, first of all, a very small categorical approach to an issue, and often becomes a huge program; second, this is something that is going on very well without us.

Senator HARKIN. In 30 States.

Ms. HARDY. Correct. I would anticipate that that would grow this year as it has grown in the last 3 or 4 years.

Senator HARKIN. Do you have any demonstrable evidence that these challenge grant moneys have been wasted?

Ms. HARDY. They haven't been spent.

Senator HARKIN. They have not been spent.

Ms. HARDY. No; they are proposed for rescission.

Senator HARKIN. What have we spent in the past?

Ms. HARDY. Nothing. It is a new program.

Senator HARKIN. We have spent nothing on the challenge grants.

Ms. HARDY. Correct, it is a new program. It was authorized in the supplemental at the end of last year.

Senator HARKIN. Congress appropriated money, $5 million, for a program that you don't think is worth it; is that right?

Ms. HARDY. Correct.

Senator HARKIN. So you propose to rescind it. However, if April 16 comes——

Ms. HARDY. Then my answer is the same as before, we will spend it. We will spend it on a formula basis, and that is that.

FISCAL YEAR 1987 REQUEST COMPARED TO 1986

Senator HARKIN. It still seems to me that your request for these programs, which all deal with child abuse, is substantially less than it has been in the past. Is that right?

Ms. HARDY. No.

Senator HARKIN. It is not less.

Ms. HARDY. No; it comes out about even for services. It may be some less when you do all the math, but it is not substantially less. Some of the formula money, for example, we believe should be in the formula grant, and not left in Washington, so there is a shift from some of these categories, but the total of $30.5 million, we feel, is just about at the same level.

Senator HARKIN. How is it that I can't understand this $39.5 million that we appropriated, and you are requesting $30.5 million. What is wrong with my math, I have $9 million less there. What is happening here?

PRERESCISSION VERSUS POSTRESCISSION

Mr. GOLDSTEIN. We are looking at the President's budget and the rescission process in the context that if, in fact, these rescissions were to go through, the amount provided in the $30.5 million actually reflects to some degree a little bit more than what we would otherwise receive for the 1986 year. This is basically what we are saying.

What is happening is that you keep going back to prior to the rescission.

Senator HARKIN. Yes; to the appropriation level.

Mr. GOLDSTEIN. That is where we part.

Senator HARKIN. You are basically requesting what the level would be, assuming the rescissions go through.

Ms. HARDY. Right.

Senator HARKIN. Which is very different from what we appropriated.

REQUESTS TO DEPARTMENT AND OMB

Mr. GOLDSTEIN. That is quite true.

Senator HARKIN. I just find it very interesting that your request to the Department is less than the Department's request to OMB.

Ms. HARDY. That is not unusual, Senator.

Senator HARKIN. It isn't?

Ms. HARDY. For me, it is not.

Senator HARKIN. In the other body over there, for 6 years I was the chairman of a subcommittee, and I don't know that I have ever seen that happen before, and that was dealing with two different departments, the Department of Agriculture and the Department of Energy. I don't know that I have ever seen that before. Maybe this is a different Department that I haven't dealt with much in the past.

Usually, it is people at your level who know the program intimately and who have some understanding of the need for the program. It is usually up the chain when they start getting cut. I have never seen it happen this way, but as I said, this may be a different Department that I haven't dealt with in the past.

Ms. HARDY. Senator, if I might, I don't think that it is a different Department. I think there are ways that we have solved and tried to address some of these issues in human development services that don't always take Federal money.

Senator HARKIN. I will agree with that.

DEVELOPMENTAL DISABILITIES

Secretary Hardy, on page 34 of your justifications, you respond to fiscal year 1986 committee report language concerning increases for developmental disabilities. This language directs that top priority be given to

training direct care workers in residential facilities. However, you state that sequestering and proposed rescissions will eliminate these increases.

Madam Secretary, a rescission does not eliminate a budget increase. It takes an approved rescission to do that. I assume again that you will follow this committee's directive in spending the extra $187,000 available after sequestration if the proposed rescission is not approved. Am I correct?

Ms. HARDY. You are correct, Senator, but I would like to add, regardless of the rescission, we believe that the whole issue of training of direct care workers will be addressed through limited supplemental grant awards to the university affiliated facilities as they come to apply this year for the dollars. So either way, the issue will be addressed.

EMPLOYMENT-RELATED ACTIVITIES

Senator HARKIN. The 1984 amendments to the Developmental Disabilities Act require that beginning in fiscal year 1987 State plans must include employment-related activities among the priority services to be divided under the plan if the appropriation for State grants is at least $50,250,000. The President's request for fiscal year 1987 for the Basic State Grant Program is $50,250,000.

My questions are two. Are the States prepared to implement the employment priority required for fiscal year 1987?

Ms. HARDY. Yes, sir; the States are prepared to implement that requirement. The Administration on Developmental Disabilities has worked with the States over the last 3 years and, beyond the States, with private industry in promoting employment of the developmentally disabled. We have set targets of employing 25,000 developmentally disabled in competitive nonworkshop employment in 1984, 50,000 in 1985, and 75,000 in 1986. We have exceeded, and we expect to exceed this year all of those targets.

The States have been very supportive. They have done a good job. I expect that most of them will be right onboard in terms of making employment a high priority under the developmental disabilities legislation.

LOCAL SERVICES FOR THE ELDERLY

Senator HARKIN. I would like to talk for a while about legal services for the elderly, and then we will go on to Head Start.

Both the House and the Senate Appropriations Committee reports direct that a minimum of $1 million be spent on national legal services activities in fiscal year 1986. Now that the 4.3-percent sequester order is in effect, you should still spend a minimum of $957,000. Yet your budget justification states, and I quote, "the amount funded will be determined by the activities contained in proposals selected through the competitive process."

Are you telling us that you have no intent of making sure that the best proposals are funded at a minimum level of $957,000?

Mr. GOLDSTEIN. What has happened in the past is that we haven't received sufficient applications to make up the amount of money to come to the $1 million figure. We are funding virtually all of the applications we are getting for the amount being requested by the applicants in this area.

Senator HARKIN. How many applications would you say that you get for this?

Ms. HARDY. I would guess that we probably get 15 to 20. Only five of the applicants are national legal service providers however, and all of these five are being funded. So we feel that we are doing a good job in terms of having legal services available to the senior citizens who need them. I think that this is the issue regardless of the number of dollars that we spend.

Senator HARKIN. Did you put out good requests for proposals? Did you send out specific requests for proposals for legal services for the elderly?

Ms. HARDY. We sent out an announcement in August, and it includes requests for legal services for seniors.

Senator HARKIN. Including a bunch of other things as well.

Ms. HARDY. Yes, sir.

Senator HARKIN. Legal services for the elderly is just one line included in there? Is it one of how many different things?

Ms. HARDY. It is one of a variety of priorities that the Congress has encouraged us to pursue.

Senator HARKIN. Under the heading of "Legal Assistance for Older Persons," there is no mention of the amount of money that is available. It states that projects are limited to $150,000 for maximum duration of 17 months. There is no mention made that there was $1 million available, or anything like that. Do you agree with that?

Ms. HARDY. It is not our practice to put in a total dollar amount that will be available for each priority area. We publish the maximum amount available for individual grants.

Senator HARKIN. Did I hear you correctly a few moments when you said, you thought the elderly people were receiving adequate legal assistance through the bar association?

Ms. HARDY. That is certainly one of the ways that we are working with the bar associations to provide legal assistance, yes, sir. We have funded what we consider rather innovative projects throughout the country at low cost, having the lawyers provide pro bono work to low-income seniors.

We believe that the legal services that are being provided are very good. What is the concern here, that we are not spending enough?

I think that it is that the services that are being delivered and the individuals who need those services are getting them. Again, it is not a question of whether it is $1 million, or if it is $50. If we could do it with $50, it would be terrific.

Senator HARKIN. We would ask, for the record, if you could provide to us all of those legal services, and whoever is providing legal services to the elderly.

Ms. HARDY. I would be very glad to do that, Senator.

[The information follows:]

LEGAL SERVICES ACTIVITIES

The Administration on Aging has funded four national legal services projects as follows:

(1) The American Association of Retired Persons, Washington, DC. National legal assistance support system to State area agencies on aging [AAA]. This project will train 1,000 lawyers, paralegals, and others involved in providing legal assistance in 20 States in substantive elderly law and advocacy skills. It will also develop two community education slide/cassette programs to educate older people, recruit and train AARP volunteers to provide service to the elderly, and to disseminate legal information to legal and aging networks. Amount: $150,000. Implementation dates: June 28, 1985–June 30, 1986.

(2) The National Senior Citizens Law Center, Washington, DC. Substantive legal support for and evaluation of elderly legal assistance. This project will provide assistance, including computer assisted legal research on substantive legal issues to the aging network. It will also develop and disseminate evaluation techniques for legal assistance providers. An evaluation manual will be produced and disseminated. Amount: $150,000. Implementation dates: June 28, 1985–June 30, 1986.

(3) American Bar Association, Washington, DC. Aging network–private bar involvement. The project addresses two law-related needs of the aging network: (1) the need for technical assistance in the delivery of legal services through private bar involvement; and (2) the need for substantive assistance with two legal issues which affect the ability of older people to stay in their homes as alternatives to institutionalization—home equity conversion and quality assurance in home care. Amount: $150,000. Implementation dates: June 28, 1985–June 30, 1986.

(4) The Center for Social Gerontology, Ann Arbor, MI. Targeted development and dissemination of tools to improve legal services for older persons. This project will assist legal services developers by preparing and providing them (1) guides for evaluating legal services for older people; (2) educational and training materials for use with private and publicly funded legal service providers. Also, the project will assist attorneys and paralegals to improve the quality of their work with older people. The project will also increase the number of private attorneys trained and willing to handle legal problems of the elderly. Amount: $156,939. Implementation dates: June 28, 1985–November 30, 1986.

The Administration on Aging funds legal services through its network of State agencies on aging and area agencies on aging. Based on sample data obtained from the national data base on aging: 96 AAA's reported funding legal services out of a total of 114 AAA's reporting any services; 2.9 percent of title III–B Older Americans Act funds awarded to AAA's were used for legal services; and the average contract amount for legal services was $30,000.

PRO BONO SERVICES

Senator BURDICK. Would the Senator yield?

Senator HARKIN. Certainly.

Senator BURDICK. What makes you so sure that you can get the pro bono services?

Ms. HARDY. What makes me sure is that we are getting pro bono services, sir.

Senator BURDICK. I used to do work pro bono in the 1930's.

Ms. HARDY. I believe there are some who have followed in your footsteps and are clearly doing excellent pro bono work.

Senator BURDICK. I am glad they are. Are you getting any support from the bar associations?

Ms. HARDY. Yes, sir; we do.

Senator BURDICK. All of them?

Ms. HARDY. No; I know of some personally, and I know that the American Bar Association [ABA] has been supportive as an organization. Whether each State bar has been supportive, I would have to inquire for you.

Senator BURDICK. Have you trial periods in this pro bono business, as to whether or not they are giving services to people, or do you have any area where you are doing this?

Ms. HARDY. We have been doing this in many of our areas. The attorneys throughout the country are working with a lot of the nonprofit organizations, with many of the organizations which we fund that may be senior oriented, or may be children or youth oriented. I think that we have a lot of good work coming from the bar associations.

Senator BURDICK. I hope you are right. I think you ought to monitor it a little bit.

Ms. HARDY. I think there are a lot of retired attorneys who are very interested in helping their colleagues who cannot necessarily afford services, and that, I think, is going to be very important in many of the retirement areas.

Senator BURDICK. We will take a look at it as the years go by.

Senator HARKIN. I would like to see the material for the record on providing legal services to the elderly.

Again, as a member of the bar, I can appreciate that the American Bar Association is involved with this. I would like to know, have they given you any indications in writing or otherwise that this isn't needed, and that they can handle it through pro bono work?

Ms. HARDY. I would have to defer to the Administration on Aging, but I have not seen a letter to that effect. In talking with many of the ABA people, they certainly have been extremely supportive of seniors, children, youth, all of our areas.

Senator HARKIN. That is not the point. You can be supportive, and you can also say that it is not enough, we just can't handle it.

Ms. HARDY. They have provided services.

LEGAL SERVICES IN IOWA

Senator HARKIN. I can tell you, in my home State of Iowa, it must be like North Dakota, we have a lot of elderly people living in small towns, and there is not this kind of legal services available to them. Yet, many times, they do need help on utility bills, for rent, for consumer fraud cases, a lot of things like that. I don't know how you can say that there is a magic lawyer out there that can help them.

We have a statewide legal service in Iowa, but I can tell you that they are hopelessly understaffed. They don't have enough money to meet one-half of the needs of the State of Iowa right now, let alone just the elderly. The Iowa bar has tried to help, but they can't do it either.

I see a discontinuity here between what I hear you saying and what my experience has been in my home State, that the bar, while they are

well-intentioned, and while they do provide some good pro bono work, it simply doesn't cover the needs out there at all, and that is why I am concerned that your activity seems to be that you are not going to spend this money for any of these proposals.

LEVEL OF FUNDING FOR LEGAL SERVICES

Ms. HARDY. No, Senator; we are going to fund good proposals, but we may not fund 1 million dollars' worth. We have good proposals that address that, and we will certainly look at funding more of them, but I am looking for quality proposals that are ones that can reach out to the seniors that you are talking about.

I think that there is another entity for the seniors that are in the real communities, or wherever they are, who need these kinds of services. We are hoping to get them in contact with their area agencies on aging, which can also provide services.

Some of the questions that you have raised, whether it is utility, consumer fraud, or whatever, may not frankly require an attorney. They may require a paralegal, or they may require some other type of assistance. We are looking to the area agencies on aging throughout the country to be able to get the seniors to these kinds of services.

Senator HARKIN. You are right, many times they don't require a lawyer, and a paralegal would do just fine, but they don't have those either. I assume that this can go for that, too, right?

Ms. HARDY. Yes; but I also believe that there are support mechanisms within the community that are there, that either we fund or we partially fund, which can also be very helpful.

HEAD START

Senator HARKIN. Let's turn to the Head Start Program. Your budget makes a claim that there will be no cut in Head Start enrollments despite either the fiscal year 1986 Gramm-Rudman cut or the fiscal year 1987 budget proposal to freeze funding at 1985 levels.

Are local Head Start project directors telling you that they can absorb these cuts without reducing the enrollees and staff?

Ms. HARDY. Yes, sir; they are. I think I need to explain to you that any decreases that are having to be absorbed at the local level amount to no more than 1.4 percent of program dollars. We have been able to take our reductions from other parts of the Head Start Program, including reprogramming of carryover balances, et cetera, so that we have a 1.4-percent across-the-board decrease in every Head Start Program. I think each one of them can absorb that without any kind of quality decrease in the program.

1986 SUPPORT FOR SPECIAL HANDICAPPED PROJECTS

Senator HARKIN. Your budget material indicates that you were forced to cut Head Start special handicapped projects from $1.8 million down to $1.098 million under the fiscal year 1986 sequestering order. That is a cut of 16.3 percent, and not 4.3 percent.

The question is, even if the law prohibited you from cutting training and technical assistance, isn't there some place where you can reprogram funds to avoid such a drastic cutback in special handicapped projects?

Mr. GOLDSTEIN. There aren't. The way the Gramm-Rudman Act was interpreted, in terms of its application to the Head Start Program, we had to take a 4.3-percent reduction to Head Start. Training and technical assistance was identified as a program project and activity. The law required us to spend at least $25 million in that area. The only other area we could have taken that 4.3-percent reduction was in the research, demonstration, and handicapped area. That was the only remaining available source, which amounted to $3.1 million. Therefore, it basically had to be applied there.

Ms. HARDY. These are not handicapped programs per se. We are not cutting the number of handicapped children in Head Start, nor are we decreasing the services to the kids who need them. This is on the support side, the academic side, perhaps the assistance side. We think that we can live with it.

Senator HARKIN. This is a 16.3-percent decrease.

Ms. HARDY. This is all together, and not just handicapped projects.

Senator HARKIN. Did you restore this money in your 1987 budget request?

Ms. HARDY. Yes.

Senator HARKIN. All of it?

Ms. HARDY. Yes.

Senator HARKIN. You are telling me that you can cut 16.3 percent from the Head Start special handicapped projects, and that it will not affect any handicapped children in Head Start, why are you putting the money back in next year?

Ms. HARDY. The way the Head Start budget is put together internally, and the line items under it, most of the dollars are going to the children. At least 10 percent by law must be handicapped in Head Start, and we have approximately 12 percent throughout the country. We will perhaps do less in the research and demonstration area. We will not have those competitive projects that you asked about earlier, doing extra studies on Head Start, doing some innovative projects with Head Start, maybe adding some different health services at different locations. We will do less of those this year. Children is what this program is about, and we are not impacting on the children with those decreases.

Next year, we are going to have the same number of children, and have requested the restoration of all the dollars sequestered in 1986.

QUESTIONS FOR THE RECORD

Senator HARKIN. Madam Secretary, we have a number of questions we would like to submit in writing for response to the record.

Ms. HARDY. I will be glad to answer them, Mr. Chairman.

Senator HARKIN. Senator Burdick, do you have any questions?

AGING NUTRITION SUPPORT

Senator BURDICK. I have one or two small ones.

Meals-on-wheels from the Administration on Aging are proposed for next year at the fiscal year 1985 level. As you know, we think that the 1985 level did not take into consideration inflation, and a number of other things. Do you expect any sites to be closed because of this level of funding?

Ms. HARDY. No, Senator; we do not expect any sites to be closed, and we expect that we will serve additional meals with a small increase for meals-on-wheels from the 1985 level.

Senator BURDICK. With the same money, or are you going to feed additional people with more money?

Ms. HARDY. We have done that historically, and we think we are going to continue to do that. There are several ways. There are management improvements such as performance-based contracting that are standard throughout the field. Second, we also have initiatives to encourage contributions at the senior centers, and the contributions have nearly doubled since 1981. We expect increased contributions to continue, and the dollars from these contributions to support additional meals.

Senator BURDICK. It is a great idea, and time will tell.

Ms. HARDY. I think that we have already been proven correct.

Senator BURDICK. Your theory applies to the services in the other areas, too?

Ms. HARDY. Yes.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator BURDICK. I am with you, and I am hoping.

Thank you.

Senator HARKIN. The questions, which I referred to earlier, will be placed in the record at this point.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

TRANSFER OF FUNDS AMONG AGING PROGRAMS

Question. States are allowed to transfer funds among the service categories of supportive services, congregate nutrition services, and home-delivered nutrition services, and have used this flexibility primarily to transfer funds from the congregate nutrition service category to other categories. Is this trend continuing and what are your interpretations as to what this means for the Title III services program in the long term?

Answer. The trend is continuing. States are more effectively targeting resources towards supportive services and home-delivered meals for the most vulnerable elderly.

LEGAL SERVICES FOR THE ELDERLY

Question. Both House and Senate Appropriations Committee Reports direct that a minimum of $1,000,000 be spent on national legal services activities in Fiscal 1986. Now that the 4.3 percent sequester order is in effect, you should still spend a minimum of $957,000. Yet your budget justification states, "The amount funded will be determined by the activities contained in proposals selected through the competitive process." Are you telling us that you have no intent of making sure that the best proposals are funded at a minimum level of $957,000?

Answer. No. Consideration will be given to all organizations which submit proposals within the guidelines specified for funding in the legal services category. To qualify for a grant award, however, the application must demonstrate that the project would build the capacity of State units on aging, area agencies on aging, and/or legal services providers to meet the needs of older people. During the past several years OHDS has received applications from four or five organizations which have met the criteria for national legal service programs. In past years all of the four to five applicants have been funded.

Question. How do you expect to comply with this Committee directive if you don't put out a specific Federal Register proposal seeking grant applications?

Answer. The Coordinated Discretionary Funds Program announcement in the Federal Register each year specifically sets legal services for older persons as a priority area. This year the priority area in the announcement dated September 4, 1985, is 6.2C.

GERONTOLOGY CENTERS

Question. The Conference Report on the Fiscal 1986 Labor-HHS bill states: "The Conferees reaffirm their interest in the long-term care gerontology centers in existence in fiscal year 1985

and direct the Administration on Aging to continue to fund these centers." Yet your budget material again equivocates on whether this directive will be carried out. Do you intend to make sure all eleven Gerontology Centers receive funding in Fiscal 1986?

Answer. In Fiscal Year 1986 the Administration on Aging (AoA) funded two Long-term Care Gerontology Centers (LTCGC) at $450,000 each. In addition, a number of centers have applied for support under the Office of Human Development Services FY 1986 Coordinated Discretionary Funds Program Announcement. Final decisions regarding funding will be made prior to the close of the fiscal year.

It is also important to note that AoA funded nine major universities in 1979 to develop these centers, and that all nine centers successfully reached the end of their project period on September 29, 1985. This ended AoA's five-year financial commitment to these ongoing, fully operational and self-supporting centers. However, AoA funded two additional centers at the Universities of Utah and Texas in 1982, is still supporting them, and intends to do so until the end of their project periods, when they will also be fully operational.

Question. Are you displeased with the performance of the Long-term Care Gerontology Centers?

Answer. No, the Centers have been quite successful in meeting the objectives they set out to accomplish. The Centers have always been informed that Federal funding would not continue indefinitely. One of the goals they were funded to achieve was self-support at the conclusion of Federal funding. In fact, the Centers have generated approximately $24 million of other resources from universities, State funds, corporate and private resources. The nine Centers, whose project periods terminated at the close of FY 1985, now have the capacity to be self-supporting.

Question. Why do you insist on making these centers compete with a lot of other groups for general grant funds in the face of the clear intent of the Appropriation Committees to earmark funds to continue their operations?

Answer. The eleven Centers have received approximately $18 million in grants from the Administration on Aging. With these and other funds, they have developed, and continue to develop, as operational centers a broad range of knowledge and expertise in the field of long-term care. The Centers have always been informed that Federal funding would not continue indefinitely. The nine Centers whose project periods have terminated now have the capacity to be self-supporting. The Administration on Aging intends to continue funding the other two until the end of their project periods when they, too, will be fully self-supporting. However, should they choose to, the nine centers may apply and compete with other projects for additional scarce dollars.

AGING RESEARCH, TRAINING AND SPECIAL PROJECTS

Question. In the past budget submissions on the Older Americans Act, the Administration has proposed large reductions in the Research, Training, and Demonstration program. Once again, your fiscal 1987 budget request would cut the program by 50 percent. Assuming the program is reduced in fiscal 1987, what priority areas would you continue to fund?

Answer. The priorities for Title IV funding under the Older Americans Act have been established as multi-year priorities as part of the HDS Coordinated Discretionary Fund Program. As outlined in the FY 1986 Federal Register Announcement (9/4/85), the major aging-related priority areas are:

- Support for Families and Community-based Care;
- Preparation for an Aging Society;
- Foundations/HDS Partnerships;
- Strengthening the Functioning of State and Locally-administered Social Services;
- Improving the Management of Human Services;
- Education, Awareness and Training in Aging.

Proposals responding to these priority areas will again be considered in FY 1987 and will be reviewed according to the merits of the applications.

ALZHEIMER'S DISEASE

Question. The 1984 Amendments to the Older Americans Act required special consideration to projects to meet the supportive services needs of persons with Alzheimer's disease and their families. What projects in this area have you undertaken and what are your plans for use of research and demonstration funds in this priority area?

Answer. In FY 1985, the following grants were made for projects to meet supportive services needs of persons with Alzheimer's disease and their families.

"Establishing a Baseline Profile of Public Knowledge and perceptions Concerning Alzheimer's Disease," University of Southern California;

"Strengthening Community Support for Alzheimer's Disease victims and their Families," Hillhaven Foundation;

"Alzheimer's Legal Support Project," New York City Department for the Aging;

"Analysis of Behavioral Programming for Alzheimer's and Other Dementia Clients," University of Chicago;

"Improving the Capacity of Primary Caregivers to Care for Rural Elderly Persons with Alzheimer's Disease and Other Related Disorders," West Virginia University;

"Telephone Networks for Alzheimer's Caregivers; An Instructional Package for Peer Support;" University of Southern California;

"Church-based Counseling Services for Older Persons with Alzheimer's Disease and Their Families," Tri-City Community Mental Health Center;

"A Model Respite Care Program for Alzheimer's Disease Victims and Their Families," Connecticut Department on Aging;

"Training and Placing In-home Respite Care Workers for Alzheimer's Patients," University of South Florida;

"An Alzheimer's Disease Partnership for Community-based Respite," The Alzheimer's Disease and Related Disorders Association of Eastern Massachusetts;

"Cooperative Approach to Information Dissemination and Development of Support Groups in Rural Areas," University of Kansas College of Health Sciences and Hospital;

"A Residential Resource Center Supporting Formal and Informal Caregivers of Alzheimer's Disease," Bureau of Maine's Elderly;

"IMPACT OF SPECIALIZED ALZHEIMER'S DISEASE DAY CARE PROGRAMS," UNIVERSITY OF SOUTH FLORIDA

During FY 1986, the Administration on Aging will be considering continuing applications from a number of past projects which had received multi-year awards. Among the applications received under the Federal Register announcement for the FY 1986 Coordinated Discretionary Funds Program there were several requests to fund projects to meet supportive services needs of persons with Alzheimer's Disease and their families.

These applications are now under consideration. Decisions regarding support for individual projects or groups of activities will be made by early May.

STATE CONTRIBUTIONS TO ELDERLY NUTRITION PROGRAM

Question. For a number of years the Administration has encouraged States to increase the amount of program income from contributions from older persons who receive supportive and congregate and home-delivered meals. What are the major barriers faced by States in increasing the amount of program income they collect for services?

Answer. First, it should be noted that voluntary contributions to programs supported with Older Americans Act funds are still increasing. The report for the first quarter of FY 1986 indicates an increase of $3.4 million in contributions as compared with the first quarter of FY 1985. Therefore, if any barriers exist, they were not significant enough to impede these recent increases in program contributions.

The only impediment which AoA has identified with respect to contributions has been the perception which some participants have that OAA-supported programs are "free" and, as a result, beneficiaries have no obligation to make voluntary donations (consistent with their abilities, of course) to defray program costs. AoA's continuing efforts to publicize the contribution opportunities are designed to overcome these perceptions.

Question. Do you expect the amount of contributions to keep increasing over the next several years, or do you expect that the amount collected from older persons will level off?

Answer. We expect the aggregate amount of contributions to continue to rise in the next several years, although the rate of increase will not be as pronounced as in previous years.

STATE ADMINISTRATION OF OLDER AMERICANS ACT

Question. The 1984 Amendments to the Older Americans Act changed the way State agencies receive funds for State Agency Administration by consolidating all Title III services and administrative funding into one allotment. States are required to assure that implementation of this new arrangement will not jeopardize funds for services. How is AoA monitoring this amount of funds States are now using for State administrative purposes?

Answer. The Administration on Aging tracks the amounts of funds used for administrative purposes through Quarterly Financial Status Reports from the State Agencies on Aging.

Question. For FY 1985 do you have estimates of the total amount of Title III funds which were used by States for Administrative purposes?

Answer. In FY 1985, the total amount of funds used by States for State Agency Activities (including the supplemental amounts awarded under Title IV - $1,870,000 - and transfers from program allotments) amounted to $31,200,000.

Question. How does this compare with FY 1984?

Answer. The total amount of funds available for State Agency activities in FY 1984 (Title III State Administration allotments, Title IV Ombudsman and Training Awards, and transfers from Title III program allotments) amounted to $30,000,000. Thus, there was a net increase of $1,200,000 for such activities in FY 1985.

Question. Is there any evidence that services funds have been reduced to pay for State Administrative functions?

Answer. Thus far from an analysis of state reports there is no evidence to suggest a decrease in services.

LONG TERM CARE OF THE ELDERLY

Question. The Administration has used Title IV funds to support the National Long-term Care Channeling Demonstration Program since 1980 and the results of this demonstration program are expected early in 1986. What can you say about the findings of this demonstration in terms of the use of community-based long-term care services and prevention of institutionalization?

Answer. The Channeling Demonstration was a rigorous test of the effectiveness of comprehensive case management as a way of containing the rapidly increasing costs of care to the elderly while providing adequate care for those in need. The program was designed to serve severely impaired older persons who require long-term care services for an extended period of time and who, in the absence of Channeling, were at high risk of being institutionalized.

In the late spring, 1986, a final summary report will be issued by HHS which will discuss the findings of this demonstration.

Question. What plans do you have to disseminate findings from this program?

Answer. The Department of Health and Human Services' Office of the Assistant Secretary for Planning and Evaluation (ASPE), coordinator of the demonstration, is responsible for dissemination of the report findings. The Administration on Aging has provided ASPE with its list of organizations which would have particular interest in the report. The list includes AoA Regional Offices, State Units on Aging, Area agencies on Aging, long-term care gerontology centers, professional organizations in the field of aging, the clearinghouses which maintain information on all reports and evaluations of AoA programs, and the appropriate Congressional Committees.

GENERAL COUNSEL OPINION

Question. Can you provide the Committee with a General Counsel's opinion that justifies your failure to comply with the law requiring reductions of no more than 4.3 percent in each "program, project, and activity".

Answer. It is the opinion of the General Counsel that the Deficit Reduction Act requires reductions of 4.3 percent in each program, project, and activity (PPA) subject to the across-the-board reduction.

The PFA listing of Aging Research, Training, and Special Projects was an attempt to comply with Report language, and still retain the competitive grant awards process. Our interpretation of the requirements, based on the PPA listing is that Research, Training and Special Projects must be reduced 4.3 percent. All activities listed in parenthesis after this item will be funded.

57-852 O—86——38

However, the levels at which such activities were funded last year is not meaningful, since final funding levels cannot be determined until proposals are received and evaluated. Funding levels for 1986 will be determined through that competitive process.

CHILD ABUSE AND DAY CARE RESCISSIONS

Question. You are proposing to rescind funds for two new programs: Child Abuse Prevention Challenge Grants and Dependent Care Planning Grants. If Congress rejects these rescissions, will you be ready to promptly award the $5,000,000 appropriated for each program?

Answer. Should Congress reject the rescission for these two programs, we will publish a notice in the Federal Register promptly informing States of the availability of funding and the procedures for applying for these grants.

Question. Will it be necessary to publish regulations for either of these programs, or do you merely distribute the funds to the States according to statutory allocation formulas?

Answer. We have determined that the statute is sufficiently clear and that no additional requirements are needed. We will publish a notice in the Federal Register announcing the availability of funding for States based on the statutory allocation formulas and other statutory requirements.

Question. Provide for the record a State-By-State list of how these funds would be allocated once the recissions expire.

Answer. A State-By-State list of allocations for the Dependent Care Planning Grants is available, and follows.

We cannot provide similar information for the Child Abuse Prevention Challenge Grants until State applications are received and the allocations are computed. Available funds will be distributed to eligible States on a reimbursement basis, with the federal government contributing 25 cents to every dollar raised by States or 50 cents per child in the State.

DEPENDENT CARE FY 1986

STATE/TERRITORY	ALLOCATION
ALABAMA	69,343
ALASKA	50,000
AMERICAN SAMOA	699
ARIZONA	53,059
ARKANSAS	50,000
CALIFORNIA	445,289
COLORADO	55,231
CONNECTICUT	54,814
DELAWARE	50,000
DIST. OF COLUMBIA	50,000
FLORIDA	190,754
GEORGIA	101,442
GUAM	2,395

STATE/TERRITORY	ALLOCATION
HAWAII	50,000
IDAHO	50,000
ILLINOIS	200,051
INDIANA	95,551
IOWA	50,573
KANSAS	50,000
KENTUCKY	64,703
LOUISIANA	77,546
MAINE	50,000
MARYLAND	75,582
MASSACHUSETTS	100,764
MICHIGAN	157,716
MINNESOTA	72,332
MISSISSIPPI	50,000
MISSOURI	87,035
MONTANA	50,000
NEBRASKA	50,000
NEVADA	50,000
NEW HAMPSHIRE	50,000
NEW JERSEY	130,604
NEW MEXICO	50,000
NEW YORK	308,219
NORTH CAROLINA	107,142
NORTH DAKOTA	50,000
NORTHERN MARIANA	379
OHIO	186,861
OKLAHOMA	57,316
OREGON	50,000
PALAU	379
PENNSYLVANIA	206,829
PUERTO RICO	56,673
RHODE ISLAND	50,000
SOUTH CAROLINA	57,351
SOUTH DAKOTA	50,000
TENNESSEE	81,977
TEXAS	277,875
UTAH	50,000
VERMONT	50,000
VIRGIN ISLANDS	2,156
VIRGINIA	97,949
WASHINGTON	75,582
WEST VIRGINIA	50,000
WISCONSIN	82,829
WYOMING	50,000
TOTAL	4,785,000

DEPENDENT CARE PLANNING AND DEVELOPMENT

Question. The administration has proposed rescinding the $5 million appropriated for FY 1986 for the dependent care program for before-and after-school child care for school age children, noting that it duplicates existing funding sources such as title XX of the Social Security Act (the social services block grant) and the administration does not want to begin a new program when it is reducing existing programs to meet deficit targets. Can funding for before-and after-school

child care be made available from existing sources (such as the SSBG) without increasing funding to provide for these services or reducing other services to free up such funds?

Answer. SSBG funds are already used by the States for child care. The SSBG is not nor should it be considered the only source of funds for school age child care in this country. The Federal government is only one partner in a national community which includes State and local governments, private corporate and nonprofit organizations, and voluntary organizations. Sources such as the SSBG, the over $4 billion in Federal funds spent every year on child care through the Child Care Tax Credit, child care provided for trainees under the Work Incentive Program, and the child care income disregard under the AFDC program, provide a base on which efforts by other members of the partnership can be built. Private employers, for instance, are increasingly becoming aware of the benefits to them of ensuring that employees have child care -- all day or before and after school -- that they can count on. Parent cooperative efforts are another approach.

IMPLEMENTING NEW PROGRAM

Question. Secretary Bowen indicated that regulations would be published this month to implement the Family Violence Prevention and Treatment Act. Why was this program signaled out for implementation, while no action has been taken to implement two other new programs: The Dependent Care Block Grant and Child Abuse Prevention "Challenge Grants"?

Answer. The President's budget requested a rescission of the funds appropriated for these two new programs. While we recognize the importance of making these services available to children, we cannot endorse the creation of categorical programs for these purposes in a time of severe budgetary constraints. States already have the authority to use their Social Services Block Grant allotments for these services. To create a new and duplicative source of Federal funding would inhibit efforts to reduce the Federal deficit.

In the event that the rescission is not acted on, we will publish a notice in the Federal Register informing States of the availability of these grants and how to apply for funding.

CHILD ABUSE AND FAMILY VIOLENCE

Question. Will eliminating the discrete child abuse authorization and funding reduce the current level of services to this population?

Answer. We do not believe it will. First, under our proposal the level of funding to States for services will not be reduced. In FY 1986, $29.8 million will be available to States under the Child Abuse Prevention and Treatment and Family Violence programs (including funds appropriated in FY 1985 and available in FY 1986 and proposed rescissions.) The new legislation will provide $30.5 million for these services.

Second, we believe that combining these programs will increase the amount of funds available to be spent on services rather than on administrative requirements, and the funds available can be used more flexibly and effectively for services delivery.

Question. Who are the anticipated target populations for the Family Crisis and Protective Services program and how do they differ from populations served under the present programs for child abuse and family violence?

Answer. Under the Family Crisis and Protective Services Program HHS will continue to provide funds for the prevention and treatment of child abuse and neglect, spouse abuse and elder abuse. -- these populations will be better served by the new program because States will have more flexibility in service delivery.

Question. What would be the structure of the new Family Crisis and Protective Services grants program (e.g., how would funds be allocated, what services would be authorized, etc.?)

Answer. The same range of services would be authorized as under the current programs. Details of the allocation formula are still being worked out, but we hope to provide a legislative proposal to the Congress very soon containing this information.

CHALLENGE GRANTS

Question. In Fiscal Year 1985, Congress appropriated $5,000,000 for initial funding of the child abuse prevention "challenge grant" program. Provide for the record a State-by-State list of the amounts States are currently entitled to under this matching grant program.

Answer. Since not all States will be eligible for these funds, this information will not be available until applications are received from eligible States and the available funds allocated based on the statutory formula. We estimate however, that approximately 20-25 States are currently eligible for reimbursement.

FAMILY VIOLENCE

Question. Your budget justification material indicates you plan to publish regulations in March to implement the Family Violence Prevention and Treatment Act, and award grants soon thereafter (p. 31). When do you expect to finish making grant awards for the entire $8.5 million appropriated to date?

Answer. As noted in the Federal Register notice published March 10, 1986, States and Indian Tribes have until May 9, 1986, to submit applications for funding. We will make grant awards as soon as possible following receipt of the applications and determination that all application requirements have been met.

Question. Your budget justification material indicates you plan to publish regulations in March to implement the Family Violence Prevention and Treatment Act, and award grants soon thereafter (p. 31) If Congress fails to go along with your legislative proposal to abolish this program through block grant consolidation, what funding level would you recommend for Fiscal 1987?

Answer. We continue to believe that the most effective use of funds is in a larger flexible grant to the States, rather than in the narrowly defined smaller program currently existing in the Family Violence statute.

Question. What is the status of your legislative proposal to create a new "Family Crisis and Preventive Services" block grant?

Answer. We are currently drafting this proposal and hope to transmit it to the Congress in the very near future. We are not proposing a block grant but rather a State formula grant which retains the important child protection and Baby Doe requirements contained in the existing statutes.

SUMMER UNEMPLOYMENT BENEFITS FOR HEAD START STAFF

Question. You are proposing that we add legislation in the appropriations bill to prohibit Head Start staff from receiving umemployment benefits in the summer months. What would the impact of your proposal be in reducing the income of Head Start staff, many of whom are struggling to support their families while earning only the minimum wage?

Answer. All Head Start employees should receive similar treatment. It is inequitable that some Head Start program staff collect between-term unemployment benefits while many others are prohibited by law from collecting between-term benefits because their programs are operated out of public school systems. It is also an inappropriate and inefficient use of the unemployment compensation system to supplement staff salaries through unemployment benefits. The unemployment compensation system is intended to assist those who are unemployed and actively seeking work, and many State laws prohibit payments to persons who are not actively seeking work and have jobs to return to. Many Head Start staff know they will be employed by the same program the following year. The use of between-term unemployment compensation benefits is costing Head Start programs $15.6 million in additional payments to State unemployment funds according to a recent study by the Department's Office of Inspector General.

Question. How much would have to be added to the Head Start appropriation to offset the loss of these unemployment benefits?

Answer. ACYF estimates that 80 percent of Head Start

employees not working in programs run by public school systems, or approximately 50,000 staff members, are receiving between-term unemployment benefits and that the average amount collected per employee is $1,000. Head Start programs, according to the Inspector General's report, contribute $15.6 million more than is minimally necessary to State unemployment funds because of the high incidence of unemployment benefit use. This $15.6 million would be saved if Head Start employees no longer received between-term unemployment benefits; however, the savings would not appear for two or three years due to the lag in the way payments to the State unemployment fund are made.

POLITICAL MANIPULATION OF CHILD ABUSE GRANTS

Question. The press has reported that up to one-half of the grants given out for Child Abuse projects were removed from the competitive system. What is you response to allegations that the National Center on Child Abuse and Neglect has been manipulating grant awards?

Answer. The allegation that the National Center on Child Abuse and Neglect has been manipulating grant awards is without foundation. The decision making process explained in each DHHS/OHDS Federal Register grant application solicitation announcement is the process which has been followed.

No grants were removed from the competitive system. As in previous years, the FY 1985 Coordinated Discretionary Funds Program was administered through a two stage preapplication and full proposal process as described in the Federal Register of August 23, 1984, pages 33530 through 33558. This process provided for the funding of applications through administrative review only after full competition in the preapplication stage.

The FY 1986 process omits only the pre-application or concept paper as described in the Federal Register of September 4, 1985, pages 35906 through 35944. The competitive review and decision making process otherwise is the same as in past years.

Question. What efforts are being made to seek out the best expert advice in awarding of child abuse prevention and treatment grants?

Answer. We have a list (computer printout) of reviewers approved by the Office of Human Development Services who are experts in the various areas of child abuse and neglect such as child protective services, research, sexual abuse, training, legal services, courts, medical and health services, education, and related disciplines. They come from both the public and private sector. The reviewers list is updated periodically during each year. Our objective is to maintain the integrity, quality and effectiveness of the process

through utilization of approved and available expert conscientious reviewers.

ADOPTION OPPORTUNITIES PROGRAM

Question. The Adoption Opportunities Program is intended to help eliminate barriers to special needs adoptions -- such as handicapped and minority youngsters. How many special needs children are legally free and awaiting adoption?

Answer. For 1986 there are an estimated 19,500 special needs children legally free and awaiting adoption through public child welfare agencies.

Question. Why are you proposing to rescind funds already appropriated to strengthen this program, since such efforts are supposedly a priority of this Administration?

Answer. We have given priority to increasing the adoption of special needs children. To this end we have funded the Adoption Opportunities program, which focuses on reducing barriers to such adoption. However, in FY 86, this program received an unneeded increase of $3 million (or 150%) over the 1985 level of $2 million. The reduction of $3.4 million would bring the FY 86 appropriation level to the President's proposed budget for FY 86, a level sufficient to fund Demonstration and Service Improvement projects, the National Adoption Exchange, and the Adoption Compact. In addition, $46 million appropriated for the Adoption Assistance program in FY 86 will be used for payments for 21,000 special needs children in adoption.

LIMITING LENGTH OF HEAD START PARTICIPATION

Question. Your Head Start budget justification material says "emphasis will also be placed on encouraging programs not to provide multiple years of service as a matter of course." Does this mean you will be putting pressure on local Head Start projects to only provide one year of service to most children -- and perhaps limiting most enrollments to 4-year olds?

Answer. We have suggested that we expect the regions to assure that those children which are selected for multiple years of service are chosen in a deliberative manner and for specific reasons. We do not intend to make Head Start available for only four year olds but rather to assure that those children enrolled at an age (three in most cases) which would result in two or more years of service are children who have such special needs that more than one year of Head Start is warranted.

Question. Exactly what limitations do you plan to impose on local grantees with respect to such matters as age of enrollees and length of service?

Answer. The Head Start Act permits Head Start programs to serve children for more than one year, and we will not implement any policy which would be in violation of that statutory provision. However, many programs are providing children with additional years of service as a matter of course and not because an assessment of the benefits to the child and family of receiving additional year(s) has been made. Each child served for an additional year is at the expense of another child not receiving any Head Start services. Therefore, we believe that multiple years of service should only be extended in those cases where the child and/or family have special needs that make an additional year of service particularly important. We will be publishing a Notice of Proposed Rule Making later in the spring explaining under what circumstances we believe multiple years of service are appropriate and what will be expected of programs in terms of the services they provide to children who are enrolled for more than one year in Head Start.

CHILD ABUSE

Question. What information do you have about the increasing incidence of child abuse?

Answer. For a number of years our continuing information source on child abuse and neglect was the number of reports made to Child Protective Service Agencies. This is based on official reports and shows a 158 percent increase in the years between 1976 and 1984. The number of official reports for 1983 and 1984 were 1,477,000 and 1,727,000 respectively. While we have witnessed increased reporting, that is not the same as increased incidence. There is an element of the increase which is a function of public education and greater willingness to report what may have been going on all along.

The National Center for Child Abuse sponsored a study of the incidence of Child abuse and neglect in 1979-80 and presently has another incidence study under way. The earlier study estimated 3.4 out of each 1,000 children are accepted by CPS agencies as having abuse and neglect problems. When the current study is complete, we will be able to compare its incidence rate with the 1980 study and determine whether incidence has increased.

Question. Why are you therefore requesting cuts below levels appropriated by Congress last year for Child Welfare Services, Head Start, and Child Abuse and Family Violence Prevention activities?

Answer. With respect to the Child Welfare Services - Title IV-B, our FY 87 budget restores the account to $200 million, the 1985 level. Also the budget of $1.075

million in the Head Start Program restores the account to the 1985 level. Both amounts represent increases over the 1986 level after Congressionally-initiated Gramm-Rudman-Hollings sequestration.

The amount proposed for Family Crisis Protective Services is an increase over the President's proposed rescission amount for FY 1986. We believe, by consolidating funds and allowing the states and localities to spend as they see fit, better use can be made of funds available for child abuse.

HEAD START UNEMPLOYMENT BENEFITS

Question. You are proposing Bill language to prohibit Head Start staff from collecting "Between-Term" Unemployment Benefits. What is the status of this legislative proposal in the the authorizing Committees?

Answer. On March the 31st, the Department will send to Congress a legislative proposal containing recommendation for reauthorization of the Head Start Act. A change to make Head Start employees ineligible for unemployment compensation during periodic break in employment is contained in that propose legislation.

Question. How many Head Start staff would be denied unemployment benefits, at what estimated total amount?

Answer. According the February, 1985 DHHS Inspector General's report, approximately 80 percent of staff not employed in public school systems are eligible to collect between-term unemployment benefits do so. We estimate that approximately 50,000 Head Start staff would not receive between-term unemployment benefits, at an average of $1,000 per employee.

Question. How do salaries of Head Start Staff -- teachers, teachers aides, and administrators -- compare with comparable positions in local school districts?

Answer. The annual salary of Head Start teachers, aides and administrators is less than that of teachers, aides and administrators in public school districts. However, a comparison of salaries between both groups of employees is problemmatic because there are major differences between Head Start employees and public school personnel in terms of qualifications and hours worked. For example, all elementary school teachers must have a college degree and a teacher certification. Head Start staff, on the other hand, are generally not college graduates (10 percent last year) and are not required to have State certification. Head Start staff generally work fewer hours and for fewer days than teachers in public schools, so that while the annual wage of a Head Start teacher is well below that of an elementary school teacher, their hourly wages are more comparable.

Our data indicate that between 1980 and 1985 public school salaries increased approximately 5 percent while those in Head Start increased by approximately 30 percent. During this same period the comulative inflation increase in the general economy was 35 percent.

As another possible bench mark, a recent study done by the Department's Office of Inspector General compared the salaries of Head Start employees with those of day care workers in the same communities and found that Head Start personnel are paid the same hourly rates slightly above their counterparts in day care.

HEAD START

Question. The Administration proposed a funding level of $1.075 billion for Head Start in FY 1987, the same amount it received in FY 1985. $28 million of this is to be for training and technical assistance activities. In proposed regulations published April 3, 1985 (P. 13253-13255), ACYF would require Head Start agencies hiring permanent employees to conduct personal and employment checks and national criminal records checks for crimes related to Child Abuse and Neglect to the extent permitted by State law. The regulations note that the DHHS intends to make additional funds available through the National Center on Child Abuse and Neglect to assist States in developing and implementing these new Head Start requirements. How do you propose to provide the same quality of services to the same number of children in FY 1987 as in FY 1985 without increasing funding?

Answer. In FY 1987 the Head Start program hopes to maintain its FY 1986 enrollment by working closely with all our grantees to assure that all Head Start programs are making maximum use of their resources. We will continue to work with our grantees to assist them in securing alternative resources so that Head Start dollars continue to be used only for those costs that cannot be paid from other sources (i.e. Medicaid, local government agencies, etc.). We will also be working with programs to assure that they maintain adequate class sizes and we expect to be able to increase the size of some Head Start classes in those programs which maintain class sizes well below the national average. We recognize that maintaining the FY 1986 enrollment level will require a considerable effort on the part of the Head Start Bureau and each individual grantee. If there are instances in which a program believes it cannot maintain enrollment without a decline in the quality of the program than we will, as always, put quality as our first consideration.

Question. Will the requested level of funding allow for salary increases for Head Start employees?

Answer. No funds in FY 1987 are available for a general pay increase for Head Start employees. Some

programs however, may chose to use program improvement or other funds to provide increases within their current project grant funds.

Question. Will the funds identified for training and technical assistance ($28 million) include continued support for the Child Development associate assessment and credentialing system?

Answer. Yes, the funds identified for training and technical assistance will continue a high level support for the child development associate assessment and credentialing system.

Question. Is the Department providing funds to assist Head Start agencies hiring permanent employees in conducting personal and employment checks and national criminal records checks for Child Abuse and Neglect-related crimes?

Answer. No, additional funds are not needed for Head Start grantees to cover these costs.

OHDS REGIONAL REORGANIZATION

Question. Please explain the specifics of the Philadelphia regional reorganization, such as how many staff have been working in the developmental disabilities area and what their new responsibilities will include. Will the same person who dealt with the Vermont Developmental Disabilities Council, for example, continue to do so?

Answer. No. The original assignee was a person with primary expertise in the financial management area and has returned to that office. A person with a child development background will now be servicing Vermont.

Question. Doesn't this approach dilute the value of the assistance provided by the regional staff to the States?

Answer. No. This approach should strengthen assistance to the States and should be much more efficient while being less intrusive. It should focus attention on the interrelationships of the child welfare efforts, mainstreaming, and special needs and gaps in services for the DD population, which tends to be the same child or families requiring child welfare services.

Question. Why wasn't notice of the reorganization in Philadelphia published in the Federal Register as it was for New York and Chicago?

Answer. The difference was that in the Philadelphia Regional Office realignment of the Administration on Aging Office was not involved while in the New York and Chicago Regional Office reorganizations the Aging Office was affected. Regions have always had the flexibility of accomplishing their mission in any efficient effective way.

Six staff members, including a supervisor, were originally assigned to DD. The supervisor will not have an active State workload. They will service the assigned States for child welfare and DD issues. This will strengthen the special needs effort.

UNIVERSITY AFFILIATED FACILITIES

In Fiscal 1985 you funded three new Satellite Centers under the University Affiliated Facilities (UAF) program and received an appropriation of $9 million. The budget request for Fiscal 1987 is $9 million.

Question. Is it your conviction that the existing network is large enough and receives adequate funding to serve this Nation's developmentally disabled citizens, train service providers, disseminate research findings and to provide technical assistance?

Answer. There are 36 University Affiliated Facilities and 7 satellites located in 36 states. In 1984, seven feasibility studies were supported resulting in the addition of 3 new satellites (University of Connecticut, University of Minnesota, and Virginia Commonwealth University) to the ADD funded UAF program. The mandated minimum for University Affiliated Facilities was raised from $150,000 to $175,000 in the 1984 legislation; satellite core awards were raised from $50,000 to $75,000 - although we currently fund satellites at $150,000.

ADD financial support to University Affiliated Facilities and Satellite Centers is for administration and organizational support. ADD funds are core awards and University Affiliated Facilities generate several times over that seed amount to operate programs which provide interdisciplinary training, exemplary services, technical assistance and dissemination. In Fiscal Year 1985, it is estimated that University Affiliated Facilities generated $12 for each ADD dollar.

Question. Do you believe that this program was overfunded in Fiscal 1985?

Answer. No, I do not believe that the University Affiliated Facility program was overfunded in Fiscal Year 1985.

Question. Do you have any plans to further expand the network so that every State may enjoy the benefits of a UAF or Satellite Center?

Answer. In Fiscal Year 1986, the Administration on Developmental Disabilities has provided the opportunity for existing Satellite Centers to convert to University Affiliated Facilities. Three satellites (University of Rochester, University of Minnesota and Virginia Commonwealth University) have indicated their intention to submit applications for review which meet the four mandated activities of a UAF. This conversion will not require additional funds. At this time there are no further plans to expand the UAF network.

Question. How have the UAF's addressed the recommendation of this Committee, which appeared in the Fiscal 1986 Appropriations Bill Report, that top priority be given to train direct care workers in residential facilities for the developmentally disabled?

Answer. The significant training needs regarding qualified paraprofessionals in the care of persons of all ages with developmental disabilities has been evident to the Administration on Developmental Disabilities (ADD) for several years. Recent studies indicate that more than 80% of the personnel in service programs who come into contact with adults who are developmentally disabled are paraprofessionals.

The Administration on Developmental Disabilities and the UAF network currently conduct many activities for improved training, career development, stability and incentives to increase residential care personnel.

In addition, the Administration on Developmental Disabilities will announce the availability of funds to University Affiliated Facilities and Satellite Centers for supplemental grants. The purpose of these grants will be to develop and implement plans to promote the recruitment and training of direct care workers in community residential settings. ADD expects to fund up to 43 supplemental projects to UAFs and Satellite Centers for a total commitment of approximately $500,000.

ADD is calling for projects that: identify skills necessary for residential direct care providers; promote recruitment of high school and undergraduate college students for careers as direct service providers; provide the education and training experience necessary to ensure quality service delivery; and facilitate the placement of trained personnel in community residential settings.

ADD through its UAF network has demonstrated a significant on-going commitment, at current budget levels, to the enhancement of residential services, including direct care personnel.

We are pleased to report that many facilities and centers are actively engaged in addressing aspects of recruitment, training and maintaining quality personnel. UAFs train trainers of entry level personnel, provide technical assistance to states and community organizations involved in the evolution of local community residential services, offer exemplary service models as community services and training sites and disseminate successful efforts for replication.

SPECIAL PROJECTS

Question. What is the status of your Special Project funds?

Answer. The Administration has proposed that Special Projects funding for 1986 be rescinded.

Question. Were any of these funds distributed to continuing grantees prior to the submission of the Fiscal Year 1987 Budget?

Answer. No funds have been distributed.

Question. What are the consequences when these funds are withheld?

Answer. To prevent the occurrence of any problems, no-cost extensions through the end of April were processed for those grantees where problems might have occurred.

ABOLISHING THE WORK INCENTIVE PROGRAM

Question. What rationale do you have for proposing elimination of these program -- to take place immediately through rescission of enacted fiscal 1986 appropriations -- only to propose legislation to require States to reestablish them in fiscal 1987?

Answer. The Work Opportunities legislation being proposed by the Administration does not reestablish the WIN program. Instead, it establishes a new approach to work activities as part of the AFDC program, an approach which focuses on job search and mandatory participation in real work activities to enhance welfare recipients' employability and earnings.

Some States currently are operating, through their welfare agencies, job search or alternative work activities (under the WIN Demonstration or related AFDC authorities) many of which would be considered allowable under the Work Opportunities Initiative. The Administration believes that such allowable activities could and would be continued, in most instances, under the new initiative.

Since Work Opportunities will be funded under AFDC beginning in FY 1987, the Administration has proposed to complete the phaseout of WIN in FY 1986, by rescinding fourth quarter funds.

Question. What incentive is there for Congress to enact your legislative proposal when the President himself has announced the Administration's study of the welfare system won't be completed until December of 1986?

Answer. Congress should implement the Work Opportunities Legislation now to give States greater flexibility in the design of their work programs and to shift the emphasis of all such programs to job search and real work activities to improve welfare recipients' employability and earnings. While it is true that the President has ordered a comprehensive study of the entire welfare system, he remains committed to the concepts embodied in the Work Opportunities Legislation and we expect such an approach would be reflected in the study's final recommendations.

Question. What good would it do to "save" $220 million by abolishing the WIN Program, when State reports indicate welfare costs would go up by double this amount?

Answer. Abolishing WIN will save $220 million, the current Federal share of WIN funding, since the costs of the Work Opportunities program, which is proposed to replace WIN, are more than offset by savings in AFDC, Medicaid and Food Stamp benefits, and by receipts from income taxes on the earnings of newly employed

participants. In AFDC, the total first year Federal/State costs are estimated at $400 million, total savings at $469 million, for net total savings of $69 million.

DIFFERENCE BETWEEN WIN AND WOI

Question. Won't the Work Opportunities Program be administered by the same welfare agencies that now administer WIN in many States?

Answer. It is the States' prerogative to hire whatever staff they feel would have the expertise to help welfare recipients obtain jobs. The real issue, however, is not whether the program would be administered by the same agencies, but what flexibility the Administrators have to fashion services that meet their needs most effectively. The Work Opportunities Program would provide that flexibility.

Question. What is different about the Work Opportunities Program that would make it more successful than WIN?

Answer. The Work Opportunities Program emphasizes job search and mandatory participation in actual work activities to enhance welfare recipients' employability and earnings. Under the Administration's proposal, States will be given flexibility in the design and operation of their work programs. States can choose from a number of employment-related activities, including Job Search, the Community Work Experience Program (CWEP), subsidized private employment, or a State-designed employment-related program, as well as participation in the Job Training Partnership Act (JTPA) training. Finally, responsibility for administering these programs would be placed with State welfare agencies, which have the greatest knowledge of AFDC recipients needs.

Question. Why abolish a program that annually places 350,000 welfare clients in jobs before legislation is enacted for a replacement program?

Answer. If Congress approves the Work Opportunites Initiative, it is anticipated that it would be available in early Fiscal Year 1987. Other programs would be available to help in the transitional phase until the new program is in effect, for example the Job Training Partnership Act and other programs under the Social Services Block Grant. It is also not correct to credit WIN with being responsible for placing several hundred thousand welfare clients in jobs each year. As the 1982 GAO report (and others before it) demonstrates a majority of WIN registrants who found jobs did so on their own with little or no assistance from WIN.

Question. Since WIN is so popular in Congress -- we had a 2 to 1 roll call vote in the Senate last year rejecting a motion to eliminate it -- why not try to reshape it more to your liking?

Answer. The Administration believes that various facets of the Regular WIN Program -- that form of WIN in effect in 43 States in 1982 and currently in effect in 28 States and other jurisdictions -- render the program ineffective and justify its elimination. These include:

— Dual Agency Administration -- 28 States and jurisdictions still share responsibility between the State welfare and employment agencies. This cumbersome approach fails to locate responsibility for reducing dependency in State welfare agencies which have the greatest knowledge of AFDC recipients' needs.

— Registration -- A significant percentage of Regular WIN funding simply pays for registering people -- not for job search or actual work experience.

— Lack of Mandatory Participation Requirement for WIN Registrants -- A high percentage of Regular WIN registrants at any point in time are unassigned to active program activities.

We believe that it makes more since to eliminate the program completely and to replace it with a new, superior approach based in part on results from WIN Demonstrations than it does to try and reshape it.

Question. How much are the States contributing now in matching funds under WIN and CWEP?

Answer. Under WIN, the Federal government provides 90%, as required by law, and the States contribute 10%.

Under CWEP, the Federal government provides 50% and is matched by 50% from the States.

Question. How much do you estimate States would have to contribute under your "mandatory workfare" legislative proposal -- for training and child care expenses?

Answer. Under Title IV-A of the Social Security Act, participants in our work programs are entitled to supportive services, such as child care, which they need to participate in our Work Opportunities Initiative, or to funds to cover their supportive services costs. State expenditures under IV-A for child care would be matched at 50 percent; funds from States Social Services Block grant could also be used. We would not match expenditures for basic education/training activities because they have not proved cost effective. Most of these activities are time consuming -- recipients can more effectively increase their employability through direct participation in work activities. If States wish to provide training they can do so without matching - currently many States heavily overmatch activities of this sort anyway.

Question. Right now, the States are contributing about $40 million under the WIN Program -- but under your new proposal, they would have to pay $200 million. How do you expect the poorest States to have an incentive to operate more expensive work programs for welfare recipients?

Answer. All States will have the same incentive to operate work programs: savings in the States' shares of AFDC and Medicaid benefit costs, and revenues from taxing the earnings of newly employed program participants. Moreover, unlike WIN where funds were limited

to the appropriated level, Work Opportunites expenditures will be matched 50 percent on an open-ended basis. For the initial year of operation, we estimate that total Federal/State AFDC costs of these program would be $400 million; total savings $469 million, and net savings of $69 million. Also, States already recognize that work programs require a greater up-front investment, since many heavily overmatch now on these activities.

REPORT ON DISCRETIONARY FUNDS

Question. Can you give this Committee a report on how discretionary funds are being spent, not just in Child Abuse Prevention Grants, but in all Office of Human Development activities?

Answer. The Office of Human Development Services uses a standard process, as required by applicable laws and regulations, in making discretionary grants. A full description of the process is contained in the HDS Grants Administration Manual (GAM). Although details may vary according to the statutory authority under which funds are made available, an overview of the process is as follows:

1. HDS publishes a program announcement in the Federal Register to inform the public of the availability of funds appropriated by Congress and to solict applications. The applications are received and processed for competitive review.

2. Experts from the field to which the funds are related review and evaluate each application according to published review criteria. The experts provide written comments on the strengths and weaknesses of each application and a numerical score. Most reviewers are from outside the Federal government.

3. Senior HDS officials, based on reviewer scores and comments - and on other information available to them - make decisions on which applications should receive funding

From Fiscal Year 1982 through Fiscal Year 1985, HDS has made some 1,100 discretionary grants under the Coordinated Discretionary Program (CDP). The CDP was established to allow HDS to coordinate applications for funds from several different statutory authorities. The grants have been made under the following subject areas:

SUBJECT	AMOUNT	NO. OF GRANTS
Adoption and Foster Care	$ 9,640,171	116
Child Abuse and Neglect	14,520,007	157
Child Care	5,707,365	52
Community and Family-Based Care	3,165,494	35
Developmental Disabilities	1,419,101	14
Dissemination and Utilization	3,354,006	21
Economic Development Strategies	683,562	3

SUBJECT	AMOUNT	NO. OF GRANTS
Elderly and Family	8,431,876	76
Employment and Income Generation	7,406,464	67
Evaluation	2,263,268	18
Gerontology Training	8,585,449	99
HDS Training	704,297	10
Head Start	2,558,925	22
Local Supply and Demand Issues	976,427	5
Management Information Systems	5,452,366	41
Miscellaneous	5,779,330	58
Non-Service Approaches to Svcs Needs	274,826	3
Primary & Secondary Prevention	941,985	12
Program Management Improvements	6,193,574	57
Public-Private Linkages	1,222,857	12
Public Innovations	1,789,694	18
Runaway and Homeless Youth	8,188,481	73
Small Business Innovation Research	144,580	5
Social Services Block Grant Trans	704,061	7
Strengthening Families	4,562,374	54
Targeting Resources	1,493,510	16
Tribal Service Needs	1,212,785	14
Volunteers	2,606,398	28
Voucher Systems	258,395	3

USE OF SECTION 1110 FUNDS

Question. What is the advantage of funding Child Welfare R&D under both the general authority of Section 1110 of the Social Security Act and the specific authority for Child Welfare R&D?

Answer. For the past four years, funds appropriated under Child Welfare Research and Demonstration have been used to support cross-cutting projects under Section 1110 of the Social Security Act. For Fiscal Year 1987, funds have been requested separately to support activities authorized under Section 1110. The request for Child Welfare discretionary activities has, therefore, been reduced by $2,400,000 and an equivalent amount has been requested for Section 1110 activities. For Fiscal Year 1987, $6,000,000 has been requested to support Child Welfare discretionary activities.

The advantage of cross-cutting projects supported with Section 1110 funds is that a single project can address areas of concern to several programs with a project which benefits several populations, thus reducing costly duplication of effort. This is a effective means to eliminate redundancy in Federally cost-supported research and demonstrations.

HEAD START

Question. You are proposing that we add legislation in the appropriations bill to prohibit Head Start staff from receiving unemployment benefits in the summer months. Apart from the merits of this proposal, why don't you seek this change in the authorizing legislation?

Answer. We are also seeking this change in the authorizing legislation. On March 31, 1986, the Department will send to

the Congress a legislative proposal for Head Start reauthorization which contains this proposed change on summer unemployment benefits.

Questions Submitted by Senator Arlen Specter

DEPENDENT CARE

Question. You are proposing to rescind $5 million for Dependent Care Planning in FY 86 thereby eliminating this new program to provide before and after school child care to school age children, because it duplicates the efforts of the Social Services Block Grant (SSBG). In Pennsylvania many day care programs have closed because of the lack of available funds. This adversely affects working mothers and women who may be enrolled in education or training programs. Given the inability of the SSBG to accommodate existing child care needs, how can you assert that the Department Care Planning and Development funding would duplicate the SSBG program?

Answer. The authority in the Dependent Care statute does duplicate the authority in the SSBG - everything for which funds may legally be used under Dependent Care can also be funded under the SSBG. What the Dependent Care program represents is another appropriations line item - a small sum of money split among the states and loaded down with many administrative and programmatic requirements, including the requirement that 40 percent of the funds be spent on resource and referral, not school age child care. In a time of tight budget constraints, we do not believe that this is an effective use of funds, nor do we believe that it represents the right approach to the problem.

The SSBG is not nor should it be considered the only source of funds for school age child care in this country. The Federal government is only one partner in a national community which includes state and local governments, private corporate and nonprofit organizations, and voluntary organizations. Sources such as the SSBG, the over $4 billion in Federal funds spent every year on child care through the Child Care Tax Credit, child care provided for trainees under the Work Incentive Program, and the child care income disregard under the AFDC program, provide a base on which efforts by other members of the partnership can be built. Private employers, for instance, are increasingly becoming aware of the benefits to them of ensuring that employees have child care — all day or before and after school -- that they can count on. Parent cooperative efforts are another approach.

MISSING AND EXPLOITED CHILDREN

Question. On March 14, 1986, the Justice Department released a report by the Attorney General's Advisory Board on Missing Children. What are your views regarding the status and treatment of runaway youths in light of the recommendations in "America's Missing and Exploited Children -- Their Safety and Their Future?".

Answer. The centers funded under the Runaway and Homeless Youth Act and other non-secure centers have an excellent record of service to vulnerable youth. Only four to seven percent of the youth served return to the streets, and some of these are served by other agencies or return home without further assistance. The centers are the first line of defense for vulnerable youth against those who would prey upon them, and they achieve their extremely high rate of success without the controls advocated by the Advisory Board.

Question. What effect did the Gramm-Rudman March 1 sequestration have on funding of the Runaway and Homeless Youth Act (RHYA)?

Answer. The Gramm-Rudman sequestration for FY 1986 had the effect of decreasing the Runaway and Homeless Youth Program Budget by $1 million. The reductions were taken in funds for Coordinated Networking Grants and research, demonstration, and evaluation projects leaving the center budget intact.

ADDITIONAL RUNAWAY AND HOMELESS YOUTH SHELTERS

Question. What progress has been made under HHS regulations for establishment of 10 additional shelters under RHYA?

Answer. The Federal Register announcement, published in early April, of the availability of funds for basic center grants in FY 1986 provides for the potential of funding as many as 10 more grants in FY 1986 than in FY 1985.

Questions Submitted by Senator William Proxmire

MEALS TO INDIAN TRIBES

Question. Last year's justifications indicated that you would be able to serve 1,402,700 meals to members of Indian Tribes in fiscal year 1985 under Section 608(a) of the Older Americans Act. You actually served only 1,175,590 meals to Indian Tribal members last year. Can you tell us what caused this shortfall?

Answer. The figures provided in last year's justification were estimates since the 1985 data was not available at that time. Current estimates are lower, since in FY 1985, 50% more tribes were funded. These new tribes incurred start up costs which reduced the amount of funds which could be used to provide meals.

CONGREGATE MEALS

Question. According to the table on page 86 of your justifications you expect program income per meal under the elderly

nutrition program to increase by about 11 percent between 1985 and 1986 -- from 55 cents to 61 cents -- but you project no increase between 1986 and 1987. Can you tell us why you project a substantial increase in program income between 1985 and 1986 but no increase in 1987?

Answer. Our initiative to increase program income has been underway for four years. This initiative has resulted in significant increases in program income. While we anticipate that the total amount of program income will continue to increase, the initial, rather substantial, rate of income increase cannot be sustained. We have also launched initiatives to increase low income and minority participation in Title III programs. These individuals are less able to increase their contributions. We expect total program income will increase, however, at a slower rate. We also expect the number of total meals to increase as a result of improved management efficiencies.

URBAN GRANTS

Question. I note that the Administration for Native Americans made significantly fewer grants to urban groups in 1985 than originally estimated. Last year's justification projected 42 such grants in 1985 while only 29 grants were made. Why was your original estimate so wide of the mark?

Answer. The Administration for Native Americans awards grants to those applicants who submit proposals which have the greatest potential for achieving social and economic self-sufficiency. The applications are reviewed and rated by outside panelists against published criteria. Each application competes for available funds against all other applications submitted. Because of the competitive nature of this process and the relatively small number of projects involved, it is quite difficult to project how many applications from any particular category, e.g. urban organizations, will be received or funded.

The Administration for Native Americans is indeed interested in encouraging maximum participation by urban organizations. Our experience has been that when these organizations do apply they compete as efficiently for our dollars as all Native American groups. In Fiscal Year 1985 we funded 44% of urban organizations applying for assistance; this is the same as the overall rate for all Native American groups applying.

HEAD START - STAFFING

Question. Last year you projected there would be 76,300 paid staff in 1986 under a Head Start program budgeted at about $1.075 billion. Your actual Head Start budget for the current year after sequestration is $35 million less than your original budget request yet your current projections show paid staff of 82,000 in 1986. Can you tell us how the Head Start program has been able to pay more staff with less money?

Answer. The data provided with the FY 1987 budget indicating 82,000 paid staff was in error. In FY 1986 we estimate there will be 78,100 paid staff. The increase in our projection from 76,300 to 78,100 is due to the additional staff that were hired as part of the FY 1985 expansion process; these staff were not included in last year's estimate which was prepared prior to completing the expansion effort.

Gramm-Rudman reductions were held to 1.4% below 1985 levels by using carryover balances, program improvement funds, and by promoting program efficiences, thus enabling projects to meet salary costs for 78,100 paid staff.

Question. Last year at this time you anticipated 624,700 Head Start volunteers would be donating their services in 1986. This estimate has dropped to 545,300 - a reduction of about 80,000. What has caused this reduction in your original estimate?

Answer. The estimate of 545,300 was also in error. Our estimate for the number of volunteers participating in the Head Start program for FY 1986 is 666,800.

HEAD START - COST PER CHILD

Question. I note that the average cost per child under the Head Start program in 1986 drops from the $2,335 proposed in last year's justifications to $2,261 under the sequester order and then jumps back up again to $2,336 next year. Can you tell us how these ups and downs will affect the quality of the average child's Head Start experience?

Answer. The decrease in average cost per child for FY 1986 is due to our intent to attempt to implement the reduction in the Head Start budget due to the sequestration order while maintaining the FY 1985 enrollment levels. In implementing the Gramm-Rudman reduction Head Start was able to use some unexpended discretionary funds so that each Head Start program needed to sustain a funding reduction of only 1.4 percent. As the President's FY 1987 budget proposes to restore the Head Start budget to its pre-Gramm Rudman funding level, we are assuming the FY 1986 funding reduction will be for one year only. It is our belief that most Head Start programs can manage the 1.4 percent funding reduction without deceasing enrollment or compromising quality, thus the reason for the changes in average cost per child shown in the budget submission.

AVERAGE GRADE

. Question. Last year in a question submitted for the hearing record I pointed out that your estimated average GS grade had jumped from a preliminary estimate of GS 10.50 to a final estimate of GS 12.68. You explained that this was primarily due

to the relatively high loss of lower grade employees. This year's justifications show an average grade of GS 10.9 for 1986. What caused your average grade to jump almost two full grades in 1985 and then fall back again in 1986?

Answer. The final estimate of GS 12.68 for 1985 was computed erroneously. The printout used to calculate this value was defective. A recent recalculation yielded a final estimate of GS 10.55, compared to 10% for 1986.

RUNAWAY AND HOMELESS YOUTH

Question. This year's justifications for the Runaway and Homeless Youth Program indicate that you served about 4,000 fewer runaway or homeless youth than you originally projected in 1985, even though you had more centers in operation than you thought you would. Can you tell us why the program was not as effective as you originally thought it would be?

Answer. Since the FY 1986 budget request was developed early in the second quarter of FY 1985, the number of centers to be funded and the number of youth to be served in FY 1985 were necessarily estimates. As the FY 1987 budget request shows, the FY 1985 figures changed marginally: we funded slightly more centers than estimated, served slightly fewer youth, and expended slightly fewer dollars than estimated.

The reason for the lag in the numbers of youth served is that in FY 1985, and even more in FY 1984, we had succeeded in funding a number of new runaway and homeless youth centers (45 new centers in FY 1984, 22 in FY 1985). We have learned that it takes a new center 12 to 18 months to become fully operational, and the slight downturn in the number of youth served is an artifact of that phenomenon.

CHILD WELFARE TRAINING

Question. Secretary Hardy, I want to congratulate you on your Office's performance in providing child welfare training. Last year you estimated you would be able to award 40 teaching grants to colleges and universities to provide training for 2,450 child welfare workers, supervisors and administrators in 1985. You actually awarded 35 grants but they provided training for 4,885 students. Can you tell us how you were able to double program output without an increase in funding?

Answer. In planning the 1985 grant program we required all applicant institutions to collaborate with State and local child welfare agencies to develop and implement training projects designed specifically to address the child welfare service needs of the State. Almost two thirds of the Federal funds available for teaching grants were awarded to projects providing direct training to child welfare practitioners, while the

remaining funds supported projects providing technical assistance for agency staff development and leadership training for administrators and managers of child welfare programs.

Our original estimate for projecting numbers of trainees was based upon information contained in program abstracts. Precise information on the number of staff to be trained was not always provided in the abstracts. Actual figures varied according to revisions negotiated in approved budgets and work plans. However, it was the increase in the number of in-service training projects that accounts for most of the increase in the actual number of child welfare personnel trained.

PRENATAL CARE

Question. Secretary Hardy, last year we discussed a clarification of the circumstances under which prenatal care can be provided to low-income women to avoid a certain amount of confusion at the state and local level. Of course, this is the kind of care that can prevent low birth weight babies.

You said you would follow up on that. Can you tell us what steps you have taken to clarify the guidelines?

Answer. The Office of Human Development Services, which I administer, has no specific programs to provide prenatal care to pregnant women. Your question to me therefore led to some confusion.

However, through other HHS operating divisions, specifically the Health Care Financing Administration and the Public Health Service, HHS does provide financial assistance to States to serve low-income pregnant women.

Under the Medicaid program, for example, States must provide medical assistance to the following categories of pregnant women:

-- pregnant women who receive cash assistance under AFDC;

-- pregnant women in two-parent families that meet AFDC income and resource requirements; and

-- first time pregnant women who meet AFDC income and resource requirements.

In addition, States have the option of extending Medicaid eligibility to individuals with income up to 133% of a State's AFDC payment standard.

The Public Health Service also provides funds to States through the Maternal and Child Health (MCH) Block Grant to support prenatal care and health services primarily for low-income pregnant mothers and children. The program's authorizing legislation defines "low income" as "income below the nonfarm income official poverty line" for an individual or family. The 1987 President's Budget request includes $478 million for the MCH Block Grant.

1206

OFFICE OF COMMUNITY SERVICES

STATEMENT OF JERROLD B. SPEERS, DIRECTOR

BUDGET REQUEST

Senator HARKIN. Now we will turn to the Director of the Office of Community Services, Mr. Jerrold B. Speers. Mr. Speers, what was the original budget request from the Office of Community Services to the Department?

Mr. SPEERS. Thank you, Mr. Chairman.

The original request was the same as the request from the Department to OMB, and also the same from OMB to the Congress.

We are requesting that the community services block grant [CSBG] be terminated, but that there be provided $3.6 million for the closeout of block grant and discretionary activities of the prior years.

TERMINATION OF THE CSBG

Senator HARKIN. You requested to close it out, and the Department supported that, and OMB supported that.

Mr. SPEERS. That is right, sir.

Senator HARKIN. It is not in the President's budget.

Mr. SPEERS. That is right.

Senator HARKIN. Your budget justification claims the community services block grant is not needed for the survival of those community action agencies which have been performing effectively. Yet a survey conducted by the National Community Action Foundation revealed that two-thirds of more than 800 local community action agencies [CAA] would close altogether if the block grant were eliminated.

Again, Mr. Speers, are you saying that two-thirds of all local community action agencies are not performing effectively?

Mr. SPEERS. The CSBG is not the sole source of Federal funding that the community action agencies have. In fact, the community services block grant represents on the average 12 percent of the funding, Federal funding, that community action agencies receive.

They receive approximately $2.4 billion from other Federal programs, such as Head Start, weatherization, low-income energy programs, Job Training and Partnership Act, and other Federal programs with basically the same purposes in mind, and that is to lessen the dependence of low-income people.

We feel that because the community services block grant represents only 12 percent of that funding that the community action agencies do

receive, if that 12 percent were not provided, or continued to be provided, it would not mean that the CAA's would close.

Senator HARKIN. The specific items that you just mentioned, the funding sources, the $2.4 billion that you have just mentioned, for winterization, meals, I suppose, what else?

Mr. SPEERS. Head Start, weatherization, Low-income Energy Program, energy assistance, Job Training Partnership Program, meals-on-wheels.

Senator HARKIN. All of that money goes, if I am not mistaken, and correct me if I am wrong, all of that money goes for the delivery of those services. I have been involved in some low-income energy assistance, going out to the homes and putting in insulation, or putting plastic on the windows, and that sort of thing. But the community services block grant money goes to support the staff to get the stuff out there. If you cut out the staff, how are you going to get it out there?

Mr. SPEERS. The community action agencies do make the argument that the community services block grant money is the money that provides administration, provides the support services for these various other programs.

Our comment on that, Senator, is that the Congress itself, in enacting these other programs, did provide for administrative moneys to be provided in these other programs, and the moneys that the CAA's use from the community services block grant for administration are duplicative of the administrative moneys that Congress itself has provided in these other programs.

For example, Head Start has 15 percent that is allowed for administration.

Further, it should be noted, and I think that it is very important to have this in perspective, the community action agencies are not the only entities that provide the services under these other programs. The other providers that are, in many respects, providing these services more effectively than the community action agencies, are able to provide these services under the overall limitations and considerations that Congress has placed on these programs.

Our contention is that the community action agencies ought to be able to emulate those other entities themselves.

PROGRAM DUPLICATION

Senator HARKIN. What you are saying is that it duplicates other programs.

Mr. SPEERS. Yes, sir.

Senator HARKIN. Last month, GAO testified that its analysis shows that the community services block grant complements, rather than duplicates, the services under the social services block grant.

What would you respond to the GAO, that they are just wrong?

Mr. SPEERS. No; I am not saying that they are wrong. I think that the GAO really is supportive of the comments that we are making. Certainly, the $335 million that goes to the community action agencies under the CSBG does, in fact, complement and supplement the services

that are being made available under these other programs. You can't take $335 million away without having that money not available to the community action agencies.

I would like to comment on the specifics of the GAO analysis. For example, they mentioned that in the Head Start Program the Head Start moneys were being utilized for the providing of the Head Start teaching, whereas the CSBG moneys were being provided for the training of teachers to be Head Start professionals. Our comment to that is, in fact, the Head Start funds can also be utilized for training professionals to operate the Head Start Program.

While we do not say that the exact activities that are being funded by the CSBG are exactly the same as the activities that would be funded by some of the other programs, we are saying that they are the same in kind as the other programs. If the priorities were found to be such that the training was necessary, that could be funded by the other programs as well as the CSBG.

We certainly don't contend that there won't be some kind of effect by taking away $335 million.

Senator HARKIN. Have you surveyed any of the community action agencies to see how many would close their doors if this were eliminated?

Mr. SPEERS. We have not asked that specific question, sir.

I would also make the comment that the GAO in past reports has found that between 30 percent and all the way up to 100 percent of the CSBG moneys are being used for administrative purposes in the community action agencies, and for the direct providing of direct services to the low-income individuals.

Senator HARKIN. I understand that, but you still have to have staff support to get the materials out there.

Mr. SPEERS. Certainly, we do, and we, again, return to the provision that Congress itself has made of administrative moneys in each of the other programs, and the fact that other providers are able to live within those administrative limits.

Senator HARKIN. What will happen if the specific agencies have to start using this money to train and to provide staff support and administrative support, what will happen to the delivery of services?

In other words, if Head Start has to start training its own teachers?

Ms. HARDY. We do, sir. I would disagree that we get any kind of training support from the CSBG, CAP, et cetera.

Senator HARKIN. You get no support.

Ms. HARDY. Not in terms of training. We train our own staff. Training dollars are within Head Start, and allocations to each of the Head Start programs.

Senator HARKIN. What did you just say?

Mr. SPEERS. Senator, let me clarify.

Senator HARKIN. There is some confusion here.

Mr. SPEERS. I was not making that claim, that it is included in the GAO preliminary report. I think that this was possibly one example

that the GAO auditor found in going to a CAP agency and asking whether or not the services were, in fact, the same. The example that he received was that they use CSBG money for training Head Start professionals, and the Head Start money for actually delivering the program.

I think that the contention of both Dorcas and myself is the same, that this is in fact duplicative money, that the Head Start moneys can be used for training and should be used for training. The CSBG is supplementing those programs.

PREPARED STATEMENT AND QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. We do have some other questions that we will submit to you for the record.

Mr. SPEERS. Thank you, Senator.

Senator HARKIN. Is there anything that you want to add before you leave.

Ms. HARDY. No; thank you very much.

[The information follows:]

STATEMENT OF JERROLD B. SPEERS

Mr. Chairman and members of the Committee, thank you for the opportunity to appear before you today to discuss the Administration's FY 1987 budget request for the Office of Community Services. The request does not include funding for the Community Services Block Grant (CSBG) program, but does include $3.6 million for the closeout of block grant and discretionary activities of prior years.

In proposing to terminate the CSBG, we do not mean to imply that the work of the community action agencies (CAAs), which deliver services to the poor under the CSBG, has not been worthwhile. Quite to the contrary, we emphatically make the point that the termination of the CSBG is not a termination of the CAAs, and that effective CAAs will continue to benefit the poor without the necessity of funds from the CSBG. The question before Congress is whether the Federal Government can continue, in the context of the fiscal emergency addressed by Gramm-Rudman-Hollings, to fund a variety of programs which, like the CSBG, are not vital to programs that aid the poor.

Any program ought to be able to pass two tests: It must be unique, that is, non-duplicative of other programs, and it must be an essential program. The CSBG Program fails both tests.

The CSBG duplicates other programs in several ways: funds are often used to provide adminstrative costs for other programs which themselves are allowed administrative costs, and it provides the same kinds of services to low income persons as other federal programs in both the block grant and discretionary portions of the program.

The 860 community action agencies (CAAs) which receive nearly 90% of the CSBG appropriation use a substantial portion of this money to help defray administrative costs incurred in delivering programs, such as Head Start, energy assistance, and job training, which are supported from other Federal sources, rather than to provide direct services.

In fiscal year 1986, the CAAs received approximately $2.4 billion from such other federal programs compared to only $335 million received from CSBG funds.

Athough the exact percentage of this duplication of administrative monies is unknown, the National Community Action Foundation, a lobbying group which represents the CAA network, states that as much as 40% of CSBG funds is used for overhead costs and that at least half of this is used to supplement the administative budgets of other programs. GAO reports have

indicated that CAAs use a range of from 30% to even 100% of their CSBG funds for administrative purposes.

It should be noted that among the thousands of service providers which deliver these programs, the CAAs are the only ones which are able to use two sources of federal funds for administration. For example, 48% of the Head Start programs, 44% of the heating programs under LIHEAP, and 93% of FEMA's emergency food and shelter programs are delivered by organizations other than CAAs. The other providers of such services either find the administrative allowances for these programs adequate, or they are able to leverage additional administrative monies from non-federal sources. Effective CAAs surely ought to be able to emulate these successes were the CSBG to be terminated.

A second kind of duplication found in the CSBG program is the use of block grant funds for direct services that are the same in kind as those provided under other federal funding authorities. Although the specific activities provided by CAAs under the CSBG may differ among the CAAs and from those provided by other sources of federal funding, the kinds of services provided-that is, those that are designed to lessen dependency and to attack the causes of poverty-are the same. Many of the same activities funded under the CSBG are funded as well under other federal programs, and the choice of the specific activities used to achieve the goals of the programs should be left to the local providers. Because the goals are the same and the specific activities used to achieve those goals may be the same, the CSBG clearly is duplicative of other, multi-billion dollar, programs. For example, in 1984 37% of CSBG funds were used for food and nutrition programs including such activities as transportation for the elderly to congregate meal sites, and delivering home meals to the elderly, ill and handicapped. But the Department of Health and Human Services also provides 650 area agencies on aging throughout the country with $336 million a year for congregate meals and $67 million for home-delivered meals. The money is used by 1000 contractors (only 91 of which are CAAs) to both buy and prepare food, deliver it to the homes of the elderly through the "Meals on Wheels" program and to transport the elderly to congregate meal sites. Similar duplicative expenditures are found in many other categories of direct services paid for from CSBG funds.

In a period of mounting federal deficits, this kind of duplication is clearly unjustified. Congress, in authorizing and appropriating funds for social service programs other than the CSBG, did not assume a CSBG

offset but provided sufficient funds to cover the federal share of all program costs, including those for administrative overhead and those for direct services. The use of two sources of federal funds to deliver essentially the same kinds of programs inflates costs and produces inefficiencies at both the federal and state level of program administration. In addition, such duplication makes it extraordinarily difficult for state and federal evaluators to track the proper use of such funds or to assess the impact of expenditures on program clients and services.

The problem of costly overlap of social services delivery systems in general, at the State and local level, was noted by the Institute for Local Self Government in its report on the CSBG in June, 1982. The Institute commented: "The human services system in most States is a patchwork of categorical programs, block grant programs and combinations of the two. The way the system has developed over seventeen years has created problems of several programs providing the same services, clients that must recieve basic services from as many as five or more different programs and certain needy populations that receive no service at all."

In a similar vein, a 1983 National Governors Association report commented: "It is a misnomer to speak of a human services system. The enormous, costly effort to provide services to individuals is actually a patchwork of activities involving many different governmental agencies at the federal, State and local level. There is enormous duplication of services and widespread inefficiency in the system, along with a failure to produce the results expected."

Nowhere is this kind of duplication more apparent than in the case of the CSBG and Social Services Block Grant (SSBG). There is clear duplication in the sense that: (1) both block grants have as one of their principal purposes the delivery of the same broad kinds of services---"human" or "social" services; (2) both block grants serve essentially the same population---people who are indigent or who have limited income; (3) both block grants have in common the goal of decreasing dependence on public assistance and encouraging self-sufficiency; and (4) both block grants require duplicative regulations and administrative mechanisms at the federal and frequently at the state level.

It is clear, and it is important to emphasize, that the CSBG is not the only program that professes as its goal an attack on the causes of poverty as distinct from the maintenance approach of the typcial welfare program.

For example, the Social Services Block Grant Act clearly states one of its purposes to be the "encouraging of each state...to furnish services

directed at the goals of (1) achieving or maintaining economic self-support to prevent, reduce or eliminate dependency (and) (2) achieving or maintaining self-sufficiency, including reduction or prevention of dependency...". Another federal program with a major purpose to move low income people toward self-sufficiency is the Job Training Partnership Act program.

An effort to consolidate the delivery of SSBG and CSBG services is already underway in a number of States. For example, a January 1982, report on the SSBG by the American Public Welfare Association notes that "Kentucky and Massachusetts are looking at ways to eliminate duplication of services provided under Title XX (now the Social Services Block Grant) and under the Community Services Block Grant" (parenthesis added).

Termination of the CSBG would not only accelerate the trend toward consolidation of CSBG and SSBG activities at the State and local levels, and render the delivery of services at these levels more efficient and less costly, but it would also produce significant savings at the federal level through the elimination of duplicative staffs and regulations. Finally, it would give the States much more flexibility in choosing providers and in developing a mix of services best suited to the unique economic and social needs of a particular State. For all of these reasons, we believe Congress should pursue the idea announced in the first sentence of the SSBG Act and merge the two block grants. The first sentence of the Act reads, in part: "For purposes of consolidating Federal assistance to states for social services into a single grant...".

Extensive duplication is also found in the "discretionary" portion of the CSBG Program. This portion, roughly 9% of the total, is used for direct federal grants to some 75-80 private and public organizations operating projects in such areas as community economic development, rural housing rehabilitation and repair, drinking water and waste water facilities improvement, and assistance to migrant and seasonal farmworkers. The activities supported by these projects are the same, in kind, as those supported from other funding sources within the Departments of Housing and Urban Development (HUD), Agriculture, Labor and the Environmental Protection Agency (EPA). For example, community-based organizations seeking funds for rural housing rehabilitation and repair projects are eligible for assistance from HUD-administered Community Development Block Grant (CDBG) Program. In FY 1985, roughly $208-260 million in CDBG funds was used for housing rehabilitation and repair projects

in rural areas. Funds for such projects are included in the Administration's FY 1987 request for $2.625 billion for the CDBG.

Similar duplication is found in funding authorities for economic development projects. In FY 1985, over $500 million in CDBG funds was expended for economic development projects throughout the country that were no different in kind from those currently funded by the CSBG. Finally, the Department of Labor is requesting, for FY 1987, $58.2 million which can be used by private and public organizations to provide employment and training services for migrant and seasonal farmworkers.

The above figures yield but one conclusion: The duplication of adminstrative staffs and federal monitoring and auditing created by the discretionary authority of the CSBG Act is wasteful and unnecessary and constitutes another reason for terminating the CSBG.

The foregoing discussion has focused on the issue of duplication . The CSBG also fails the test of essentiality. It is essential neither to the provision of a social safety net for the poor nor to the continued operation of the community action agencies. Its funding represents only a fraction -- less than 1% -- of the multi-billion dollar programs, such as AFDC, food stamps, and Medicaid, which make up the true social safety net and which Congress has exempted from any reductions under Gramm-Rudman-Hollings. In its FY 1987 budget request, the Administration is asking for more than $80 billion for a variety of income-tested and need-based benefit programs. Nor are the CAAs the only providers of those programs. Only $17 billion of the $80 billion represents funding for approximately 15 federal programs which use CAAs, along with thousands of other public and private organizations, as service providers; and of those programs only about 15% of the benefits and services are provided by the CAAs. From such figures it is clear that the CSBG is hardly essential to the provision of the safety net for the poor and that none of the safety net programs would be seriously affected by termination of the CSBG.

Nor is the CSBG needed for the survival of those community action agencies which have been performing effectively. This is evident from the fact that the CSBG accounts, on average, for only 12% of CAA funding. Eighty six percent or $2.4 billion of CAA funds -- including money for salaries and operating expenses -- derives from other federal funding authorities. Only 2% was supplied by State and local governments and the private sector. To

the extent that additional funds may be desirable to supplement programs administered by the CAAs, it is incumbent on these agencies to seek additional support from the state and local governments and to mobilize more private sector funds. State and localities are, in general, in much better fiscal shape than the federal government and should be able to provide more assistance than in the part for those community action agencies activities deemed essential essential by a particular state or local government. According to a fiscal survey conducted in July, 1985 by the National Association of State Budget Officers, the nation's States ended FY 1985 with a balance of about $5.4 billion, while estimates for FY 1986 place the ending general fund balance at about $4.2 billion surplus.

The argument is often made that the CAAs utilize the CSBG to leverage other funds. Yet 86% of their funds derives from other federal programs with separate Congressional authorizations and appropriations and which would continue to be funded or not regardless of the existence of the CSBG.
The termination of the CSBG would create a powerful incentive for true leveraging by the stimulation of private sector contributions and would probably result in a substantial increase in support from such sources.

In conclusion, Mr. Chairman, the proposal to terminate the CSBG is a proposal to eliminate a non-essential program which is simply duplicative of other far more substantial federal programs to help the poor. Its elimination would mean a savings of over $1 billion over a three year period. At a time when the Congress and this nation are desperately seeking ways to reduce and eliminate an annual deficit of over $200 billion, and when even truly essential programs are being asked to sacrifice, there is simply no justification for continuing to fund the CSBG.

Questions Submitted by the Subcommittee

BUDGET REQUEST

Question. Mr. Speers, what was the original budget request from the Office of Community Services to the Department?

Answer. The Office of Community Services' budget request to the Department was $3,612,000 for salaries and expenses of 36 federal employees to monitor close-out of the Community Services Block Grant program.

Question. What was the Department's request to OMB?

Answer. The Department's request to OMB was also $3,612,000 and 36 positions for purposes of closing out the Community Services Block Grant program.

CLOSING COMMUNITY ACTION AGENCIES

Question. Your budget justification claims the Community Services Block Grant (CSBG) is not needed for the survival of those Community Action Agencies (CAAs) which have been performing effectively. Yet a survey conducted by the National Community Action Foundation revealed that two-thirds of more than 800 local CAAs would close altogether if the block grant were eliminated. Are you saying that two-thirds of all local CAAs in the country are not performing effectively? Have you surveyed CAAs to see how many would close their doors if the CSBG were eliminated?

Answer. In answer to the first question, no, we are not saying that two thirds of all local CAAs in the country have not been performing effectively. Nor do we believe that two thirds of the CAAs will close down without CSBG funds.

In discussing CAAs, it is important to distinguish between two criteria for judging effective performance: (1) the degree to which CAAs have attacked the causes of poverty and have moved poor persons from poverty to self-sufficiency and (2) the degree to which CAAs have performed successfully as deliverers of social services aimed at palliating the effects of poverty.

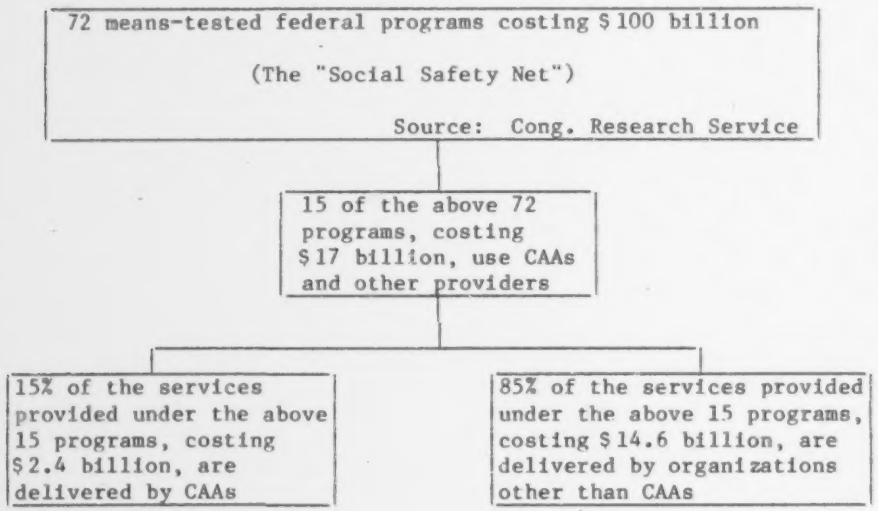
We are aware of no evidence that CAA activities, over the years, have had any significant impact on the causes of poverty. On the other hand, we have no reason to believe that most CAAs have not been, by and large, as effective as a whole range of other service providers in delivering federally-funded benefits to the poor. We believe that termination of the CSBG---which constitutes only 12% of CAA dollar resources---would provide an incentive for CAAs to trim unnecessary costs and become even more efficient and effective in delivering social services.

In answer to the second question, we have not surveyed CAAs to see how many would close their doors if the CSBG were eliminated, although we have received informal estimates from a number of states that are not nearly as pessimistic as those provided by the National Community Action Foundation. North Dakota, for example, believes that all of its CAAs would survive while California seems confident that two thirds of their 46 CAAs would survive the loss of the CSBG, and more if funds are provided from other sources. The March

20, 1986 GAO report on the CSBG has come to no conclusion on this issue. According to the report, all but three of 16 CAA's surveyed said that "they either would provide only categorical services which had administrative funding available or they would close." The GAO does not state how many said they would close. In the words of the report "How the loss of CSBG funds would effect CAAs is not certain at this time". One of the imponderables mentioned in the report was the degree to which States and localities would provide assistance.

The California case is instructive in that, in the view of State officials, the CAAs which would be most at risk are those which depend almost entirely on the CSBG. This is an important point since, as noted above, the CSBG--which is roughly $335 million--accounts on average for only 12% of the total CAA funding nationwide. Over the years CAAs have been able to diversify their portfolios to a point where 86.6% of their funding or $2.4 billion derives from some fifteen other federal programs. All of these programs save one (USDA's commodities distribution program) contain administrative cost allowances in their budgets which collectively should be enough to cover CAA salaries and overhead. For example, the overhead allowance for Head start is 15%, for the Community Development Block Grant 20%, for LIHEAP 10%, for JTPA 15% etc.

In this connection, it is important to note that CAAs are not the only deliverers of services under the fifteen programs. The following diagram will help put the CAA role in perspective.


72 means-tested federal programs costing $100 billion
(The "Social Safety Net")
Source: Cong. Research Service
15 of the above 72 programs, costing $17 billion, use CAAs and other providers
15% of the services provided under the above 15 programs, costing $2.4 billion, are delivered by CAAs
85% of the services provided under the above 15 programs, costing $14.6 billion, are delivered by organizations other than CAAs

As can be seen from the above diagram, alongside the CAAs are thousands of other organizations at the local level delivering to the poor the same types of services funded from the same federal programs, as are delivered by CAAs. These organizations, unlike the CAAs, cannot tap an extra source of federal funds for administrative overhead. They have found a way to either do the job within the limits set by Congress or to leverage the additional monies needed from other sources. Of course some CAA services will

have to be curtailed. We are not implying that CAAs will be able to find enough replacement monies to do all of the things they have been doing under the CSBG. But surely effective CAAs ought to be able to emulate the successes of other service providers in the search for funds to keep them operating. The States' relationship to CAAs could be critical here.

First, States will continue to have the option transferring up to 10% of LIHEAP funds to the SSBG to support a continuation of high-priority programs formerly funded under the CSBG. In fiscal year 1984, 30 states transferred approximately $94 million from LIHEAP to five other block grants funded by the Department. In fiscal year 1987, up to $210 million will be available to the states for transfer.

[In addition, states will have the authority to transfer to LIHEAP part or all of the $2.098 billion Exxon restitution fund which has just been distributed to the states. This should enhance the states' ability to transfer more money from LIHEAP to the SSBG to cover former CSBG activities deemed essential.]

Second, according to the 1986 Fiscal Survey of the States prepared by the National Governors' Association and the National Association of State Budget Officers, the states' general fund year-end balances for fiscal year 1987 (including "rainy day" funds) are projected to be $6.1 billion. Although the Survey notes that states "that project small ending balances are unlikely to pick up federal responsibilities", it also points out that "states that are generally better off financially have responded to the imminent federal cuts".

Finally, CAAs can and should do more to leverage private sector resources. At the present time, cash and in-kind donations to the CAAs account for less than 2%, on average, of the total CAA budget. Termination of the CSBG should furnish CAAs with an incentive to do much more than they have done in the past to tap the private sector potential.

GAO REPORT ON COMMUNITY SERVICES BLOCK GRANT

Question. For several years, your budget has proposed elimination of the CSBG, claiming it duplicates other programs such as the Social Services Block Grant (SSBG). Yet last month GAO testified that its analysis shows that the CSBG complements, rather than duplicates, services under the SSBG. How do you respond to the GAO study? What specific evidence do you have of duplication and overlap in programs administered by community action agencies (CAAs)?

Answer. We believe that the findings in the preliminary GAO report on the CSBG released on March 20, 1986 (as well as an earlier GAO report dated September 28, 1984) provide strong support for the Administration proposal to terminate funding for the CSBG. In what follows, we shall first discuss, in the context of the GAO reports, the issue of the overlap between the CSBG and the SSBG, and second, a different kind of duplication between the CSBG and federal funding authorities other than the SSBG.

While there are some differences between the CSBG and the SSBG,

the Administration contends that these are minor and do not justify two entirely separate administering bureaucracies and two sets of regulations at the federal level and, in many cases, at the State level. The overlapping character of the two grants is found in the statutory purposes of each grant, the populations served and the types of services provided.

With respect to the statutory purposes, while it is true that the CSBG provides funds for "community-based programs offering health, nutrition, housing and employment-related services", the CSBG Act requires these services to be provided in order to "ameliorate (i.e. attack) the causes of poverty in communities within the States". Elsewhere, the statute directs that CSBG funds be used for "a range of services and activities having a measurable and potentially major impact on causes of poverty in the community". This underlying purpose of CSBG activities is quite consistent with the historical objective of community action agencies which was "to focus resources on the goal of enabling low-income people to become fully self-sufficient" (Economic Opportunity Act of 1964, as amended).

The first two of the five statutory goals of the SSBG also relate to the achievement of self-sufficiency. According to the statute, SSBG services are directed at:

"(1) Achieving or maintaining economic self-support to prevent, reduce, or eliminate dependency;

(2) Achieving or maintaining self-sufficiency, including reduction or prevention of dependency."

With respect to the populations served, although the CSBG is directed by its statute toward persons below the poverty line while the SSBG specifies no income limitations, in practice, services under both grants are targeted to indigent or low-income people, including single adults, children, families and elderly persons.

Finally, there is a basic similarity in the types of services provided under the two grants. Both provide "human" or "social" services to those who lack sufficient income to meet their needs, whether this lack be temporary or permanent. While there is not a significant amount of duplication in the exact services offered by the CSBG and SSBG, both block grants are now being used to support activities so closely related they should logically be put under one grant.

An excellent example of this kind of "duplication" is cited in the above mentioned GAO report. The GAO found that a social services agency in Vermont was providing day-care services while the local CAA was using CSBG funds to support the training of day-care personnel. This is, first of all, an instance of duplication in the sense that SSBG regulations authorize the use of SSBG funds to pay for the training of day-care workers. Second, it is an example of duplication in the sense that the services provided in Vermont from the SSBG and CSBG are organically related. The GAO states that the services "complement" rather than duplicate each other. But it is precisely the complementary character of the services funded for the two block grants which is at the root of our proposal to con-

solidate them. Five years ago approximately sixty categorical programs with services that complemented each other were folded into ten block grants, producing substantial savings at all levels of government. In the interest of economy, efficiency and flexibility, Congress should finish the job by pursuing the idea announced in the very first sentence of the SSBG Act and merging the two block grants. The first sentence of the Act reads, in part: "For the purposes of consolidating Federal assistance to states for social services into a single grant...".

Thus far, I have focussed on the extent to which the CSBG duplicates the SSBG, not in terms of the precise services now provided under the two grants, but in terms of the overlap in the range of services that could be funded from the two grants. But the CSBG is also duplicative of other Federal programs. This kind of duplication is found in both administrative costs and costs for direct services.

CSBG DUPLICATION OF OTHER FEDERAL PROGRAMS

With respect to the use of CSBG funds for duplicative administrative costs, the National Community Action Foundation (NCAF), the lobbying arm of the CAA network, found that at least 40% of CSBG funds are used not for direct services to the poor but for administrative overhead. The NCAF contends that half of this is used for CAA "management" expenses and half to supplement the administrative costs incurred by CAAs in delivering services to the poor under other federal programs such as Head Start, the Low Income Home Energy Assistance (LIHEAP) program, and the Job Training and Partnership Act (JTPA) program.

Similarly, in 1984 the GAO surveyed 47 organizations receiving CSBG funds in 13 states, and found that the amount of CSBG funds used to pay administrative costs of other programs ranged from 2% to 100%. According to the report: "Fifteen providers used at least 25% of their funds to administer other programs such as Head Start and the Emergency Food Assistance Program. For example, Self-Help, Inc., in Brockton, Massachusetts, said about 80% of its CSBG funds were used to administer other programs...(The) West Central Development Corporation in Harlan, Iowa...used almost all of its CSBG funds to support other federal programs." These findings of substantial use of CSBG funds to help administer other federal programs were confirmed in the second GAO report on the CSBG released on March 20, 1986. The GAO surveyed 16 CAAs in eight states and found that 11 CAAs used roughly 70% of their CSBG funds for direct services and roughly 30% for administrative expenses, while the remaining five CAAs used from 31% to 58% of CSBG funds for administration.

However, all but two of the approximately fifteen federal programs which use CAAs as service providers already contain, in their own budgets, adequate allowances to cover administrative costs. For example, the overhead allowance for Head Start is 15%, for the Community Development Block Grant 20%, for LIHEAP 10%, for JTPA 15%, etc. These programs use as service providers, many other organizations besides CAAs. In fact, CAAs deliver only around 15% of the total volume of services. Other providers either find the administrative allowances already provided for these programs suf-

ficient, or they are able to leverage additional administrative monies from non-federal sources. CAAs are the only providers we are aware of which are able to use two sources of federal funds for administrative support of the same program.

Two exceptions to this pattern are the surplus commodity food program funded by USDA and the emergency food and shelter program funded by the Federal Emergency Management Administration (FEMA).

Under the commodities program, USDA makes available each year approximately one billion dollars worth of surplus foodstuffs to organizations serving the poor. The federal government pays for the initial purchase and storage of these commodities, and bears the entire administrative burden of packaging them in sizes convenient for households and shipping them to the States. In 1983 Congress provided, through the Temporary Emergency Food Assistance Program (TEFAP), an additional $50 million to be used for administrative costs at the State and local level. However, given the size of the Federal contribution to the basic program and the urgent need to pare back Federal spending, the Administration is requesting termination of TEFAP in 1987.

We do not believe that termination of TEFAP and the CSBG will materially affect the commodities distribution program. Prior to the enactment of TEFAP, the commodities program was successfully operated for over a year, using State and local government and private resources to administer the program. Local providers other than CAAs were able to distribute food without TEFAP or CSBG funds. For example, thirty percent of the commodities, were (and still are) distributed by food banks which rely almost exclusively on non-federal funds.

The second federal program which uses CAAs and which places a low cap (2%) on administrative costs is FEMA's emergency food and shelter program. In FY 1985, only 7% (467) of FEMA providers were CAAs. The remainder were churches and other non-profit groups. The presence of CSBG funds as a source of administrative money does not appear to have played a major role in the selection of FEMA's service providers.

Another duplicative use of the CSBG is found in the use of CSBG funds for direct services that are no different from those provided under a number of other federal programs. For example, two categories of CSBG-funded services mentioned in the most recent GAO report---"providing home meals for the elderly, ill and handicapped" and "helping individuals obtain financial assistance for housing"---are identical with services furnished under other programs funded by DHHS and HUD.

In 1984 HHS' Administration on Aging (AoA) gave $67 million to 650 area agencies on aging throughout the country to provide home-delivered meals ("Meals on Wheels") for the elderly, ill and handicapped. The money was used by 1,000 contractors both to buy and prepare food and deliver it to the homes of the elderly, and to transport the elderly to congregate meal sites. Of the 1,000 contractors, only 91 were CAAs. But, in addition, many other CAAs used for identical activities a significant portion of the 37% of CSBG funds expended on food and nutrition services.

The CSBG also duplicates other Federal housing assistance authorities. Under the Community Development Block Grant (CDBG), states are given wide discretion on the use of CDBG funds for Public Housing Authorities and other organizations, including CAAs, to help individuals obtain financial assistance to repair and rehabilitate dilapidated housing units and to revitalize neighborhoods through economic development projects. In FY 1987, the Administration is requesting $902 million in CDBG funds for states and $1.7 billion for cities to be used for these purposes.

Studies by the National Community Action Agency Directors' Association and the National Governors' Association indicate that, on average, CAAs use 8% or more of their funds for activities that could be conducted using other federal authorities. Pennsylvania, for example, required CAAs to expend at least 50% of their CSBG funds on employment and training services (in duplication of many DOL programs) and on economic development (in duplication of the CDBG). Arkansas mandated that at least 30% of all CSBG funds be expended on economic development and/or housing activities while North Carolina required CAAs to allocate 40% of CSBG funds to housing and employment projects. From FY 1983 through FY 1986, $77 million in CDBG money was targeted toward emergency shelter acquisition, shelter rehabilitation and shelter operations, while roughly $60 million of CSBG money has been used annually over the same period for emergency food and shelter activities many of which, on the shelter side, overlap the CDBG-funded activities.

Finally, that part of the CSBG---the so-called "discretionary" portion (roughly 9% of the total appropriation)---which is administered directly by the Office of Community Services, duplicates funding authorities for identical programs operated by other federal agencies such as the Department of Housing and Urban Development, the Environmental Protection Agency and the Department of Labor. Details on duplication in the CSBG's discretionary activities are included in the Opening Statement.

To summarize, the CSBG is duplicative of other federal programs in at least four ways:

1. The CSBG overlaps the SSBG.

2. The CSBG overlaps the administrative allowances authorized for many other federal programs.

3. The CSBG overlaps the direct services component of many other federal programs.

4. The discretionary portion of the CSBG overlaps a number of other federal programs.

Nothing in the GAO report released March 20, 1986 is inconsistent with the Administration's claims of duplication.

At a time when the Congress and the nation are desperately seeking ways to reduce and eliminate an annual deficit of over $200 billion, and when even truly essential programs are being asked to sacrifice, there is simply no justification for continuing to fund the essentially duplicative Community Services Block Grant.

ADMINISTRATIVE COSTS OF COMMUNITY ACTION AGENCIES

Question. I just received a report from the 14 Connecticut Community Action Agencies (CAAs).

Contrary to your allegations about high administrative costs, this report indicates that only 5.8% of total funding is used for management.

The report shows CAAs are more efficient in administering such delegated programs as Low-Income Home Energy Assistance than other Connecticut agencies. (The cost per application is only $25, compared to $45 for equivalent State-administered fuel assistance programs).

Do you have specific evidence to refute the Connecticut data?

Answer. With respect to the statement that Connecticut CAAs use only 5.8% of their total funding for management, we are unable to comment sensibly until we know how the term "management" is defined. According to the National Community Action Foundation, on average, CAAs nationwide devote at least 20% of their CSBG funds to "management" of the CAAs and another 20% to "administrative" costs incurred in delivering other federal programs. The GAO found that the use of the CSBG for administration ranges from 30% at some CAAs to 100% at others. One of the difficulties in trying to precisely measure administrative costs is that there is no standard definition of the term. Reports on the CSBG indicate that the definition of administrative costs frequently varies from state to state and often from program to program. It is essential, therefore, to know how Connecticut distinguishes between "management" and "administrative" costs on the one hand, and between "administrative" and "programmatic" costs on the other, before interpreting the Connecticut data.

Second, it is important to know whether the figure of 5.8% is a percentage of the total CSBG monies passed on by the state of Connecticut to the CAAs, or a percentage of the total monies received by CAAs from all sources. If it is the latter, this fact, unless supplemented by further information, does not shed light on our main concern: how much of the CSBG do individual CAAs use for management/administration and to what degree does such use duplicate the monies available for administration from other federal programs which use CAAs as service providers?

With respect to the statement that the cost per application for energy assistance is less for CAAs than for other providers, again the paucity of information makes it impossible to comment. Were the applications for the same kinds of services, or do CAAs provide one type of assistance and the state-administered programs another? What factors were used to compute the cost per application: salaries only, or salaries and other overhead including CSBG and LIHEAP administrative funds?

We understand that the report in question was prepared by the Low Income Planning Agency which represents the 14 CAAs in Connecticut. The Agency has agreed to send us a copy of the report and we hope to be able to prepare a response to your question within the

next few weeks. In the meantime, we would like to emphasize that the evidence we do have is drawn from various studies of the CSBG which reflect what is going in the nation as whole. It could well be that the situation in Connecticut is exceptional rather than typical.

TASK FORCE ON THE HOMELESS

Question. What are your plans for the Task Force on the Homeless if fiscal 1987?

Answer. The Office of Community Services' (OCS) 1987 administrative budget request provides for salaries and expenses of six positions to support the Task Force.

Question. What budget and staff are planned for fiscal 1986 and 1987?

Answer. The current administrative budget request includes $311,000 and six positions for staff support to the Task Force in both 1986 and 1987.

Question. Where will you get the money to finance this Task Force in the absence of a direct appropriation from Congress?

Answer. In the event there is no direct appropriation to OCS in 1987, and if the Secretary wishes for the Task Force suport staff to continue operations, funding will have to be provided from other sources within the Department's administrative budget.

Questions Submitted by Senator Arlen Specter

ELIMINATION OF THE COMMUNITY SERVICES BLOCK GRANT

Question. You are requesting the elimination of the Community Services Block Grant program because you believe it duplicates existing efforts. Yet in testimony before the House Committee on Education and Labor on February 24, 1986, J. William Gadsby of the U.S. General Account Office (GAO) reports that a GAO analysis shows that in most instances CSBG supported services do not duplicate those provided by the local social service agencies. Rather, CSBG funds are often targeted to fill specific needs. How do you explain the conflicting analyses concerning the duplicative nature of CSBG funded services?

Answer. We believe that the findings in the preliminary GAO report on the CSBG released on March 20, 1986 (as well as an earlier GAO report dated September 28, 1984) provide strong support for the Administration proposal to terminate funding for the CSBG. In what follows, we shall first discuss, in the context of the GAO reports, the issue of the overlap between the CSBG and the SSBG, and second, a different kind of duplication between the CSBG and federal funding authorities other than the SSBG.

While there are some differences between the CSBG and the SSBG, the Administration contends that these are minor and do not justify two entirely separate administering bureaucracies and two sets of

regulations at the federal level and, in many cases, at the State level. The overlapping character of the two grants is found in the statutory purposes of each grant, the populations served and the types of services provided.

With respect to the statutory purposes, while it is true that the CSBG provides funds for "community-based programs offering health, nutrition, housing and employment-related services", the CSBG Act requires these services to be provided in order to "ameliorate (i.e. attack) the causes of poverty in communities within the States". Elsewhere, the statute directs that CSBG funds be used for "a range of services and activities having a measurable and potentially major impact on causes of poverty in the community". This underlying purpose of CSBG activities is quite consistent with the historical objective of community action agencies which was "to focus resources on the goal of enabling low-income people to become fully self-sufficient" (Economic Opportunity Act of 1964, as amended).

The first two of the five statutory goals of the SSBG also relate to the achievement of self-sufficiency. According to the statute, SSBG services are directed at:

"(1) Achieving or maintaining economic self-support to prevent, reduce, or eliminate dependency;

(2) Achieving or maintaining self-sufficiency, including reduction or prevention of dependency."

With respect to the populations served, although the CSBG is directed by its statute toward persons below the poverty line while the SSBG specifies no income limitations, in practice, services under both grants are targeted to indigents or low-income people, including single adults, children, families, and elderly persons.

Finally, there is a basic similarity in the types of services provided under the two grants. Both provide "human" or "social" services to those who lack sufficient income to meet their needs, whether this lack be temporary or permanent. While there is not a significant amount of duplication in the exact services offered by the CSBG and SSBG, both block grants are now being used to support activities so closely related they should logically be put under one grant.

An excellent example of this kind of "duplication" is cited in the above mentioned GAO report. The GAO found that a social services agency in Vermont was providing day-care services while the local CAA was using CSBG funds to support the training of day-care personnel. This is, first of all, an instance of duplication in the sense that SSBG regulations authorize the use of SSBG funds to pay for the training of day-care workers. Second, it is an example of duplication in the sense that the services provided in Vermont from the SSBG and CSBG are organically related. The GAO states that the services "complement" rather than duplicate each other. But it is precisely the complementary character of the services funded for the two block grants which is at the root of our proposal to consolidate them. Five years ago approximately sixty categorical programs with services that complemented each other were folded into

ten block grants, producing substantial savings at all levels of government. In the interest of economy, efficiency and flexibility, Congress should finish the job by pursuing the idea announced in the very first sentence of the SSBG Act and merging the two block grants. The first sentence of the Act reads, in part: "For the purposes of consolidating Federal assistance to states for social services into a single grant....".

Thus far, I have focussed on the extent to which the CSBG duplicates the SSBG, not in terms of the precise services now provided under the two grants, but in terms of the overlap in the range of services that could be funded from the two grants. But the CSBG is also duplicative of other Federal programs. This kind of duplication is found in both administrative costs and costs for direct services.

CSBG DUPLICATION OF OTHER FEDERAL PROGRAMS

With respect to the use of CSBG funds for duplicative administrative costs, the National Community Action Foundation (NCAF), the lobbying arm of the CAA network, found that at least 40% of CSBG funds are used not for direct services to the poor but for administrative overhead. The NCAF contends that half of this is used for CAA "management" expenses and half to supplement the administrative costs incurred by CAAs in delivering services to the poor under other federal programs such as Head Start, the Low Income Home Energy Assistance (LIHEAP) program, and the Job Training and Partnership Act (JTPA) program.

Similarly, in 1984 the GAO surveyed 47 organizations receiving CSBG funds in 13 states, and found that the amount of CSBG funds used to pay administrative costs of other programs ranged from 2% to 100%. According to the report: "Fifteen providers used at least 25% of their funds to administer other programs such as Head Start and the Emergency Food Assistance Program. For example, Self-Help, Inc., in Brockton, Massachusetts, said about 80% of its CSBG funds were used to administer other programs...(The) West Central Development Corporation in Harlan, Iowa...used almost all of its CSBG funds to support other federal programs." These findings of substantial use of CSBG funds to help administer other federal programs were confirmed in the second GAO report on the CSBG released on March 20, 1986. The GAO surveyed 16 CAAs in eight states and found that 11 CAAs used roughly 70% of their CSBG funds for direct services and roughly 30% for administrative expenses, while the remaining five CAAs used from 31% to 58% of CSBG funds for administration.

However, all but two of the approximately fifteen federal programs which use CAAs as service providers already contain, in their own budgets, adequate allowances to cover administrative costs. For example, the overhead allowance for Head Start is 15%, for the Community Development Block Grant 20%, for LIHEAP 10%, for JTPA 15%, etc. These programs use as service providers, many other organizations besides CAAs. In fact, CAAs deliver only around 15% of the total volume of services. Other providers either find the administrative allowances already provided for these programs sufficient, or they are able to leverage additional administrative monies from non-federal sources. CAAs are the only providers we

are aware of which are able to use two sources of federal funds for administrative support of the same program.

Two exceptions to this pattern are the surplus commodity food program funded by USDA and the emergency food and shelter program funded by the Federal Emergency Management Administration (FEMA).

Under the commodities program, USDA makes available each year approximately one billion dollars worth of surplus foodstuffs to organizations serving the poor. The federal government pays for the initial purchase and storage of these commodities, and bears the entire administrative burden of packaging them in sizes convenient for households and shipping them to the States. In 1983 Congress provided, through the Temporary Emergency Food Assistance Program (TEFAP), an additional $50 million to be used for administrative costs at the State and local level. However, given the size of the Federal contribution to the basic program and the urgent need to pare back Federal spending, the Administration is requesting termination of TEFAP in 1987.

We do not believe that termination of TEFAP and the CSBG will materially affect the commodities distribution program. Prior to the enactment of TEFAP, the commodities program was successfully operated for over a year, using State and local government and private resources to administer the program. Local providers other than CAAs were able to distribute food without TEFAP or CSBG funds. For example, thirty percent of the commodities, were (and still are) distributed by food banks which rely almost exclusively on non-federal funds.

The second federal program which uses CAAs and which places a low cap (5%) on administrative costs is FEMA's emergency food and shelter program. In FY 1985, only 7% (467) of FEMA providers were CAAs. The remainder were churches and other non-profit groups. The presence of CSBG funds as a source of administrative money does not appear to have played a major role in the selection of FEMA's service providers.

Another duplicative use of the CSBG is found in the use of CSBG funds for direct services that are no different from those provided under a number of other federal programs. For example, two categories of CSBG-funded services mentioned in the most recent GAO report---"providing home meals for the elderly, ill and handicapped" and "helping individuals obtain financial assistance for housing"---are identical with services furnished under other programs funded by DHHS and HUD.

In 1984 HHS' Administration on Aging (AoA) gave $67 million to 650 area agencies on aging throughout the country to provide home-delivered meals ("Meals on Wheels") for the elderly, ill and handicapped. The money was used by 1,000 contractors both to buy and prepare food and deliver it to the homes of the elderly, and to transport the elderly to congregate meal sites. Of the 1,000 contractors, only 91 were CAAs. But, in addition, many other CAAs used for identical activities a significant portion of the 37% of CSBG funds expended on food and nutrition services.

The CSBG also duplicates other Federal housing assistance authorities. Under the Community Development Block Grant (CDBG),

states are given wide discretion on the use of CDBG funds for Public Housing Authorities and other organizations, including CAAs, to help individuals obtain financial assistance to repair and rehabilitate dilapidated housing units and to revitalize neighborhoods through economic development projects. In FY 1987, the Administration is requesting $902 million in CDBG funds for states and $1.7 billion for cities to be used for these purposes.

Studies by the National Community Action Agency Directors' Association, and the National Governors' Association indicate that on average, CAAs use 8% or more of their funds for activities that could be conducted using other federal authorities. Pennsylvania, for example, required CAAs to expend at least 50% of their CSBG funds on employment and training services (in duplication of many DOL programs) and on economic development (in duplication of the CDBG). Arkansas mandated that at least 30% of all CSBG funds be expended on economic development and/or housing activities while North Carolina required CAAs to allocate 40% of CSBG funds to housing and employment projects. From FY 1983 through FY 1986, $77 million in CDBG money was targeted toward emergency shelter acquisition, shelter rehabilitation and shelter operations, while roughly $60 million of CSBG money has been used annually over the same period for emergency food and shelter activities many of which, on the shelter side, overlap the CDBG-funded activities.

Finally, that part of the CSBG---the so-called "discretionary" portion (roughly 9% of the total appropriation)---which is administered directly by the Office of Community Services, duplicates funding authorities for identical programs operated by other federal agencies such as the Department of Housing and Urban Development, the Environmental Protection Agency and the Department of Labor. Details on duplication in the CSBG's discretionary activities are included in the Opening Statement.

To summarize, the CSBG is duplicative of other federal programs in at least four ways:

1. The CSBG overlaps the SSBG.

2. The CSBG overlaps the administrative allowances authorized for many other federal programs.

3. The CSBG overlaps the direct services component of many other federal programs.

4. The discretionary portion of the CSBG overlaps a number of other federal programs.

Nothing in the GAO report released March 20, 1986 is inconsistent with the Administration's claims of duplication.

At a time when the Congress and the nation are desperately seeking ways to reduce and eliminate an annual deficit of over $200 billion, and when even truly essential programs are being asked to sacrifice, there is simply no justification for continuing to fund the essentially duplicative Community Services Block Grant.

Question. Although you assert that the elimination of the CSBG will not result in the termination of Community Action Agen-

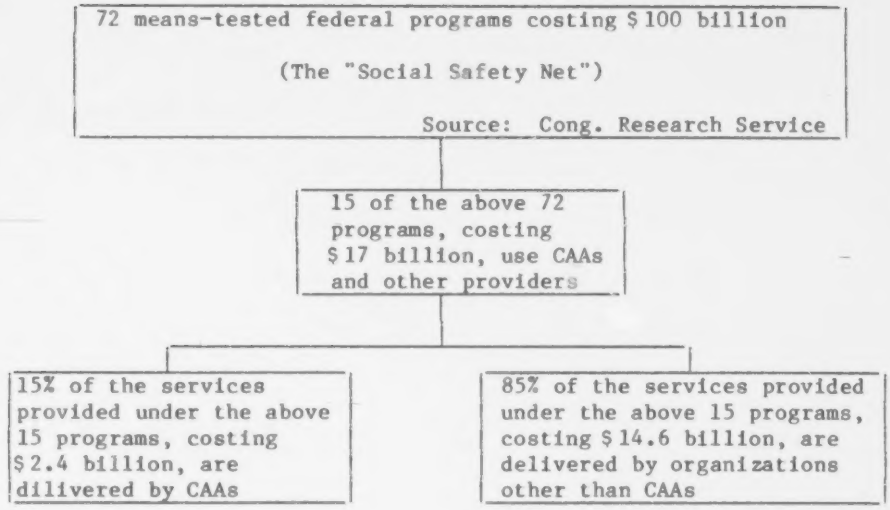
cies (CAAs), the loss of CSBG funding would result in the closing of 29 out of 34 CAAs in Pennsylvania. State and local governments would be unable to replace lost CSBG funds. How do you propose that these services, which are badly needed by senior citizens and the poor be continued? Do you have a report on the extent to which CSBG funded services in Pennsylvania duplicate existing services? I would like for you to provide me with that report.

Answer. We have no report on the extent to which CSBG-funded services in Pennsylvania duplicate existing services. Our claim of duplication between the CSBG and other other federal programs refers to the pattern nationwide and is based on various studies of the CSBG prepared by the Urban Institute, the National Governors' Association, the National Community Action Agency Directors Association and the GAO.

We believe, for the reasons given below, that most CAAs would continue to function if the CSBG were terminated. With respect to the number of CAAs which would be forced to close their doors, we think some forecasts being made by states are unduly pessimistic and underrate the ability of effective CAAs to survive. Not all states are as pessimistic as Pennsylvania. North Dakota, for example believes that all of its CAAs would survive while California seems confident that at least two thirds of their 46 CAAs would survive the loss of the CSBG, and more if funds were provided from other sources. The March 20, 1986 GAO report on the CSBG has come to no conclusion on this issue. According to the report, all but three of 16 CAAs surveyed said that "they either would provide only categorical services which had administrative funding available or they would close." The GAO does not state how many said they would close. In the words of the report "How the loss of CSBG funds would effect CAAs is not certain at this time". One of imponderables mentioned in the report was the degree to which States and localities would provide assistance.

The California case is instructive in that, in the view of State officials, the CAAs which would be most at risk are those which depend almost entirely on the CSBG. This is an important point since, as noted above, the CSBG---which is roughly $335 million---accounts on average for only 12% of the total CAA funding nationwide. Over the years CAAs have been able to diversify their portfolios to a point where 86.6% of their funding or $2.4 billion derives from some fifteen other federal programs. All of these programs save one (USDA's commodities distribution program) contain administrative cost allowances in their budgets, which collectively should cover CAA salaries and overhead. For example, the overhead allowance for Head Start is 15%, for the Community Development Block Grant 20%, for LIHEAP 10%, for JTPA 15% etc.

In this connection, it is important to note that CAAs are not the only deliverers of services under the fifteen programs. The following diagram will help put the CAA role in perspective.


72 means-tested federal programs costing $100 billion
(The "Social Safety Net")
Source: Cong. Research Service
15 of the above 72 programs, costing $17 billion, use CAAs and other providers
15% of the services provided under the above 15 programs, costing $2.4 billion, are dilivered by CAAs
85% of the services provided under the above 15 programs, costing $14.6 billion, are delivered by organizations other than CAAs

As can be seen from the above diagram, alongside the CAAs are thousands of other organizations at the local level delivering to the poor the same types of services funded from the same federal programs, as are delivered by CAAs. These organizations, unlike the CAAs, cannot tap an extra source of federal funds for administrative overhead. They have found a way to either do the job within the limits set by Congress or to leverage the additional monies needed from other sources. Of course some CAA services will have to be curtailed. We are not implying that CAAs will be able to find enough replacement monies to do all the the things they have been doing under the CSBG. But surely effective CAAs ought to be able to emulate the successes of other service providers in the search for funds to keep them operating. The states' relationship to CAAs could be critical here.

First, states will continue to have the option transferring up to 10% of LIHEAP funds to the SSBG to support a continuation of high-priority programs formerly funded under the CSBG. In FY 1984, 30 states transferred approximately $94 million from LIHEAP to five other block grants funded by the Department. In FY 1987, up to $210 million will be available to the states for transfer.

(In addition, states will have the authority to transfer to LIHEAP part or all of the $2.098 billion Exxon restitution fund which has just been distributed to the states. This should enhance the states' ability to transfer more money from LIHEAP to the SSBG to cover former CSBG activities deemed essential.)

Second, according to the 1986 Fiscal Survey of the States prepared by the National Governors' Association and the National Association of State Budget Officers, the State general fund year-end balances for fiscal year 1987 (including "rainy day" funds) are projected to be $6.1 billion. Although the Survey notes that states "that project small ending balances are unlikely to pick up federal responsibilities", it also points out that "states that are generally better off financially have responded to the imminent federal cuts".

Finally, CAAs can and should do more to leverage private sector resources. At the present time, cash and in-kind donations to the CAAs account for less than 2%, on average, of the total CAA budget. Termination of the CSGB should furnish CAAs with an incentive to do much more than they have done in the past to tap the private sector potential.

STATEMENT OF JOHN J. O'SHAUGHNESSY, ASSISTANT SECRETARY FOR MANAGEMENT AND BUDGET

ACCOMPANIED BY:

THOMAS S. McFEE, ASSISTANT SECRETARY FOR PERSONNEL ADMINISTRATION

JOHN T. HOPKINS, DIRECTOR, DIVISION OF THE OFFICE OF THE SECRETARY BUDGET SERVICES

INTRODUCTION OF ASSOCIATES

Senator HARKIN. Mr. O'Shaughnessy.

Mr. O'SHAUGHNESSY. Thank you, Mr. Chairman.

Let me introduce the individual on my right as Mr. Thomas McFee, the Assistant Secretary for Personnel, and the individual on my left is Mr. John T. Hopkins, the Director of the Office of Budget for the Office of the Secretary.

I am pleased to be here before you today to present the fiscal year 1987 budget request for general departmental management for the Department of Health and Human Services. The budget request represents the resource requirements needed to operate the general departmental management components in the second year following the streamlining that occurred in fiscal year 1985. As such, it is based upon the management improvements and efficiencies which have been instituted over the past 2 years.

The appropriation request of $108 million and 2,242 full-time equivalent staff is a decrease of $10 million and 48 full-time equivalent staff from the comparable 1986 levels. Added to the requests for transfers from the trust funds, the total resources in fiscal year 1987 will be $135.8 million compared to the fiscal year 1986 postsequestering level of $126.1 million.

The reduction of personnel will be achieved by managing hiring and employment in the Office of the Secretary staff divisions. The fiscal year 1987 budget justification reflects this management policy through staff reductions below the fiscal year 1985 level, and the post-Gramm-Rudman-Hollings 1986 figures.

Offsetting the dollar savings from the staff reductions are built-in increases for meeting general inflation costs, for salary increases, and for continuing selected management improvement projects.

Our fiscal year 1987 request continues funding for special projects activities underway in fiscal year 1986 but delayed due to budget reduc-

tions required under the fiscal year 1986 sequestration provisions of the Gramm-Rudman-Hollings legislation.

These projects include the financial/administrative integrated management system designed to reduce the cost of the Department's accounting, procurement, and related management systems by improving their efficiency and by eliminating competing, outdated, or overlapping existing systems; and the personnel consolidation and automation initiative designed to reduce the number of separate servicing personnel offices in the Department and, through the use of computers, to carry out more efficiently certain personnel and payroll workloads.

PREPARED STATEMENT

I have a number of other figures before me, Mr. Chairman, but perhaps you would rather get to them through questions that you might like to ask on this account.

[The statement follows:]

STATEMENT OF JOHN J. O'SHAUGHNESSY

Mr. Chairman and members of the committee: I am pleased to be here before you today to present the fiscal year 1987 budget request for the general departmental management appropriation of the Department of Health and Human Services.

This budget request represents the resource requirements needed to operate the general departmental management components in the second year following the streamlining which occurred in fiscal year 1985. As such, it is based upon the management improvements and efficiencies which have been instituted over the past 2 years. The appropriation request of $108,319,000 and 2,242 full-time equivalent [FTE] staff is a decrease of $10,140,000 and 48 FTE's from the comparable fiscal year 1986 level. Added to the requested transfers from the trust funds, total resources in fiscal year 1987 will be $135,819,000 compared to the fiscal year 1986 postsequestering level of $126,115,000.

The reduction of personnel will be achieved by managing hiring and employment in the Office of the Secretary staff divisions. The fiscal year 1987 budget justification reflects this management policy through staff reductions below the fiscal year 1985 level and the post-Gramm-Rudman-Hollings fiscal year 1986 figure. Offsetting the dollar savings from the FTE reductions are builtin increases for meeting general inflation costs, for salary increases, and for continuing selected management improvement projects.

Our fiscal year 1987 budget request continues funding for special projects activities underway in fiscal year 1986 but delayed due to budget reductions required under the fiscal year 1986 sequestration provisions of the Gramm-Rudamn-Hollings legislation. These projects include: (1) the financial/administrative integrated management system [FAIMS], designed to reduce the cost of the Department's accounting, procurement, and related management systems by improving their efficiency and by eliminating competing, outdated, or overlapping existing systems; and (2) the personnel consolidation and automation initiative, designed to reduce the number of separate servicing personnel offices in the Department and, through the use of computers, to carry out more efficiently certain personnel and payroll workloads. Each of these projects promise to reduce Federal administrative costs throughout the Department's operating divisions while improving the quality and timeliness of accounting, procurement, personnel, and payroll support services.

In addition to the $108.3 million in direct appropriation the fiscal year 1987 budget justification requests that $27,500,000 be transferred to general departmental management from the Social Security and Medicare trust funds. The $27,500,000 in transfer will defray the cost of payroll, payment management, accounting, and other services provided by the Office of the Secretary in support of the Social Security and Medicare Programs. The $27,500,000 represents an increase of $19,500,000 over the fiscal year

1986 transfer level, and is justified by the significant payroll, payment management, and other workloads performed on behalf of the trust fund programs. This increase in trust fund transfers does not mean that the amount of trust fund-related services provided by the Office of the Secretary will increase substantially from fiscal year 1986 to fiscal year 1987, but rather simply reflects a more accurate accounting of the value of such services already being provided on the behalf of the Social Security and Medicare Programs. The requested increase in transfers brings the GDM appropriation in line with other departmental management appropriations (Office of the Inspector General, Office for Civil Rights) that have increased trust fund transfers in recent years in order to more accurately reflect the portion of their work performed on trust fund activities.

Resources requested in this appropriation support those activities that are associated with the Secretary's roles as policy officer and general departmental manager, as well as those that provide direct specialized staff support services performed on a centralized basis in the OS for the operating divisions. No amounts for new programs or major new initiative are included. The resources requested will allow the Secretary to carry out his responsibilities, as well as permit efficient and timely centralized support services, while meeting the President's goals of reduced Federal spending and a smaller deficit burden to the taxpayer.

In many ways the managerial improvements made over the past several years have eased the transition of the OS into the Gramm-Rudman-Hollings era. By the elimination of overlapping responsibilities, reductions in staff levels, emphasis on the use of automation to achieve productivity gains, and the commitment to providing services efficiently, the OS has anticipated many of the organizational changes made necessary by this legislation. Yet much of what we began in the last 2 years remains to be done. The fiscal year 1986 sequestration order has meant the delay of the two special projects which I described earlier. Completion of these projects is absolutely essential to achieve future reduction in administrative costs throughout the Department.

The level of resources requested in this appropriation will continue to build OS operations on modern management principles while reducing the cost to the taxpayer of unnecessary and duplicative overhead expenses.

I urge your approval of this request and thank you for your consideration.

APPROPRIATION REQUEST

Senator HARKIN. Thank you very much, Mr. O'Shaughnessy.

You have an appropriation request here for departmental management of $135.8 million. Is that correct?

Mr. O'SHAUGHNESSY. That is the total level of resources to be expended by the "General departmental management" account.

Senator HARKIN. In fiscal year 1985, it was $131.9 million.

Mr. O'SHAUGHNESSY. In fiscal year 1985, it was $140.2 million, Mr. Chairman.

Senator HARKIN. For the item called departmental management?

Mr. O'SHAUGHNESSY. General departmental management, yes. The comparable figure for fiscal year 1986 is $126.1 million.

Senator HARKIN. What about fiscal year 1987?

Mr. O'SHAUGHNESSY. It is $135.8 million.

Senator HARKIN. You have $126.1 and we have $136.4 million.

Mr. O'SHAUGHNESSY. In fiscal year 1986?

Senator HARKIN. That is exactly right. I can't see a figure of $126.1 million in here.

Mr. HOPKINS. If you would bear with us for just 1 second, Mr. Chairman.

Senator HARKIN. I have a total of $136,449,000, including $8 million from trust funds.

Mr. HOPKINS. The $126,115,000, Mr. Chairman, excludes $19.6 million of proposed rescissions, and $6.2 million in sequestering in fiscal year 1986, and that may account for some of the discrepancy.

Senator HARKIN. That is what it is. The sequester, you have to do that, but not the rescission.

I assume that your answer would be the same as Ms. Hardy's, if we don't approve the rescission, you will go ahead and disburse.

Mr. O'SHAUGHNESSY. Absolutely, yes.

Senator HARKIN. What was your original budget request to the Department for departmental management?

Mr. O'SHAUGHNESSY. We can provide that for the record, sir.

Mr. HOPKINS. The Department's original request was the same as the request made to OMB, which was approximately $5 million above the levels that you see before you today. It was $141 million as compared to the $135.8 million.

Senator HARKIN. So OMB cut $5 million.

Mr. O'SHAUGHNESSY. That is right.

Senator HARKIN. The Department's request was the same as yours?

Mr. O'SHAUGHNESSY. Basically, yes.

Senator HARKIN. What would happen if you had to absorb a $5 million cut?

Mr. O'SHAUGHNESSY. The change that was made was mainly to achieve lower staff levels for the Office of the Secretary, and they will be accomplished through attrition and hiring restrictions.

GRAMM-RUDMAN REDUCTIONS

Senator HARKIN. Mr. O'Shaughnessy, under Gramm-Rudman, you will have sequestered $5.8 million. I note that you are restoring almost $3 million of these cuts for fiscal year 1987.

Mr. O'SHAUGHNESSY. That is correct, sir.

Senator HARKIN. What are you restoring?

Mr. O'SHAUGHNESSY. Mainly two projects related to automation, one having to do with common accounting and related fiscal systems in the Department in order to develop a new, comprehensive system for financial management in the Department; and, second, for a consolidated personnel system.

Senator HARKIN. I think that you have probably answered this: How will employees be affected by the $2.8 million in cuts in 1987?

Mr. O'SHAUGHNESSY. We don't expect that the reductions will affect existing personnel since they will be taken through attrition and hiring restrictions.

REGIONAL OFFICE STUDY

Senator HARKIN. At last year's hearing, you informed the committee that a study was underway to evaluate the efficient delivery of services in the regional offices.

Please summarize the results of that study and any changes in the management structure that you are contemplating in your regional offices.

Do you contemplate any changes in structure in the regional offices?

Mr. O'SHAUGHNESSY. In terms of the number of offices, at this point there are no plans for any major changes. There may be some changes eventually. We did have a recommendation inside the Department to take one component, the Food and Drug Administration, and limit somewhat the number of regional offices for that component in order to get greater efficiency. Then there were a number of other isolated instances in which certain functions were going to be reduced.

That has not been implemented yet inside the Department; I cannot make a prediction as to whether it will or will not happen at this point. I can provide, for the record, all information about what the recommendations have been, and where we stand in the Department.

Senator HARKIN. Two questions from Senator Proxmire that I wanted to ask.

DEBT COLLECTION TARGET

Mr. O'Shaughnessy, last year's justifications talked of efforts to achieve estimated collections of $1.7 billion in outstanding debt in 1986, with a reduction in delinquencies of $67 million. Is $1.7 billion still your debt collection target? If not, what is your new target?

Mr. O'SHAUGHNESSY. In 1986, our estimate is that the collections will be $1.733 billion. The amount of reduction in delinquencies would be a reduction from a 1985 level of $457 million down to $379 million, so that is $78 million, I believe.

Senator HARKIN. Your estimate of delinquency reductions in 1986 has now fallen to $24 million. Can you tell us why you were not able to reach your original goal?

Mr. O'SHAUGHNESSY. I am not sure where the $24 million comes from, sir. The numbers I have indicate that from 1985 to 1986, the delinquencies will have been reduced by $78 million.

Senator HARKIN. Can you submit that for the record?

Mr. O'SHAUGHNESSY. Yes; we will do that, sir.

[The information follows:]

DELINQUENCY REDUCTIONS IN FISCAL YEAR 1986

The amount of $24 million for reduction in delinquent accounts in fiscal year 1986 by the Department of Health and Human Services listed on page 32 of the departmental management fiscal year 1987 justification to the Congress is an error. The correct figure is $78 million. The revised fiscal year 1986 estimate of total delinquencies for the Department is $379 million. This estimate is $78 million less than the end of fiscal year 1985 balance of delinquent accounts of $457 million.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. I will submit the rest of these questions for the record.

Mr. O'SHAUGHNESSY. Thank you, sir.

Senator HARKIN. Thank you very much, Mr. O'Shaughnessy.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

GRAMM-RUDMAN SEQUESTRATION

Question. Mr. O'Shaughnessy, under Gramm-Rudman you will have sequestered $5.7 million in FY 1986. How will employees be affected by the cut in FY 1986?

Answer. There will be no furloughs or RIFs in the Office of Secretary. That policy has been firmly stated by Secretary Bowen. At most, these reductions may cause employees some minor inconvenience at work, such as not being able to travel or being short of office supplies.

REDUCTION IN FIELD MANAGEMENT

Question. Your budget for FY 1987 reduces the field management activity by almost 25% (18 full time equivalents). What is the rationale behind such a large decrease?

Answer. The positions being eliminated perform public affairs, intergovernmental affairs and other overhead support functions. The rationale for the staff reduction in this area is that these activities duplicate activities of the Operating Divisions or of central offices agencies. The Department will rely on the Operating Divisions and their field office staff components, and on other Office of the Secretary Headquarters staff to perform these functions.

Question. Can you achieve that big a cut without a RIF? How?

Answer. We are looking very carefully at all job openings in the Department and throughout the Federal government in order to assist incumbents in their search for employment. We believe we will be successful in locating jobs for all affected employees. This should avert the need for any involuntary employee separations.

OFFICE OF THE SECRETARY - 30% LOSS SINCE 1981

Question. Since 1981 you have reduced the size of the Office of the Secretary by over 30%. What has this done to the Operating Divisions of the Department and the Department as a whole?

Answer. We have conducted a rational and humane streamlining of the Office of the Secretary which has decreased inefficient and unnecessary duplication of effort and helped cut the cost of the Federal government. We decentralized or eliminated functions which were no longer required to be concentrated in Departmental Management. These actions have made the Department more easily manageable and less top heavy.

Question. Have you had to reduce or stop any essential services since 1981?

Answer. Essential services such as payroll and litigation support are still provided. We have reduced layers of management and are automating some functions in order to maximize efficiency and productivity.

Question. What are your plans for the future?

Answer. We are continuing to look at our operations with an eye towards keeping our productivity high and our costs down. It is not an overnight process. Our first efforts in this direction coincided with the Grace Commission recommendations when we streamlined the Office of the Secretary. We believe there is still room for improvement, and we will be considering further refinements in the future.

MARY BABB RANDOLPH CANCER CENTER

Question. One of the special projects for which you are requesting a rescission is the Mary Babb Randolph Cancer Center in West Virginia. You may assume that this rescission will not be approved. When may we expect release of the $4.5 million so that the University can get on with its work?

Answer. The amount appropriated for this project has been reduced by $193,000 under the Gramm-Rudman sequestration. The remaining $4,307,000 will be obligated by the end of fiscal year 1986.

TRUST FUND INCREASE

Question. For the past six years Departmental Management has received $8 million per year from the Health Care Financing Administration (HCFA) trust fund. In FY 1987 you are requesting $27,500,000 from the trust funds, and you have explained this increase in your prepared statement. This Committee is concerned, however, that the trust funds not become a source of deficit reduction in HHS accounts. Please provide the Committee with a breakdown of all HHS use of trust funds for administrative purposes, and show how this has changed since 1980.

Answer. For the past several fiscal years the General Departmental Management (GDM) appropriation has received a total of $8 million in reimbursements from four separate trust funds. The following table displays the breakout, by trust fund, of trust fund usage for administrative purposes by GDM, the Office of Inspector General (OIG), and the Office for Civil Rights (OCR).

Trust Fund Administrative Cost Transfers
($ in 000s)

Trust Fund	FY 1980	FY 1981	FY 1982	FY 1983	FY 1984	FY 1985	FY 1986*	FY 1987	% Change FY 80-87
HCFA									
Health Insurance:									
GDM	1,494	2,242	1,459	1,520	1,520	1,216	1,216	4,180	+ 180%
OCR	2,109	1,904	1,827	1,903	1,903	2,251	3,901	3,901	+ 85%
OIG	791	1,140	1,097	1,140	1,140	2,600	3,900	10,400	+ 1,215%
(Sub-total)	(4,394)	(5,286)	(4,383)	(4,563)	(4,563)	(6,067)	(9,017)	(18,481)	(+ 320%)
Supplemental Health Ins:									
GDM	1,887	2,478	1,613	1,680	1,680	1,824	1,824	6,270	+ 232%
OCR	183	212	204	212	212	-	-	-	- 100%
OIG	974	1,380	1,324	1,380	1,380	8,000	12,000	10,000	+ 902%
(Sub-total)	(3,044)	(4,070)	(3,141)	(3,272)	(3,272)	(9,824)	(13,824)	(16,270)	(+ 434%)
SSA									
Old Age & Survivors Ins:									
GDM	3,600	5,319	3,456	3,600	3,600	3,472	3,472	11,935	+ 232%
OCR	176	164	157	165	164	99	99	99	- 44%
OIG	1,806	2,580	2,476	2,580	2,580	9,000	13,500	18,000	+ 897%
(Sub-total)	(5,582)	(8,063)	(6,089)	(6,345)	(6,344)	(12,571)	(17,071)	(30,034)	(+ 438%)
Disability Ins:									
GDM	1,200	1,795	1,152	1,200	1,200	1,488	1,488	5,115	+ 326%
OCR	60	71	67	71	71	-	-	-	- 100%
OIG	636	900	864	900	900	400	600	1,600	+ 152%
(Sub-total)	(1,896)	(2,766)	(2,083)	(2,171)	(2,171)	(1,888)	(2,088)	(6,715)	(+ 254%)
Total Transfers:									
GDM	8,181	11,834	7,680	8,000	8,000	8,000	8,000	27,500	+ 236%
OCR	2,528	2,351	2,255	2,351	2,350	2,350	4,000	4,000	+ 58%
OIG	4,207	6,000	5,761	6,000	6,000	20,000	30,000	40,000	+ 850%
(Sub-total)	(14,916)	(20,185)	(15,696)	(16,351)	(16,350)	(30,350)	(42,000)	(71,500)	(+ 379%)

*Figures do not include 4.3% reduction due to sequestration.

FAMILY SUPPORT ADMINISTRATION

Question. On March 18, 1986, Secretary Bowen announced a major consolidation of six Department of Health and Human Services programs into a new Family Services Administration. Please describe the process by which the decision was made and tell us who was involved in recommending the restucturing.

Answer. Recognizing that one of the central and most important structures of American society is the family, and realizing that no single organization focused primarily on the problems and needs of, and assistance for, low-income families, the Secretary announced a reorganization to create the Family Support Administration (FSA). FSA will merge into a single operating division six of the major HHS programs assisting disadvantaged families; all are principally state or locally administered.

The Secretary, with the assistance and advice of his principal advisors, decided on this reorganization because it will:

-- Provide a central locus to administer the major income assistance and related programs for non-elderly, low-income families.

-- Elevate the concern with and responsibility for assistance to low-income families. The Administrator of FSA will report directly to the Secretary.

-- Give states a single point of contract on matters concerning these programs.

-- Provide a single locus and critical mass of staff and funds for research, evaluation and demonstration activities concerning performance and administration of programs assisting poor families.

QUESTIONS SUBMITTED BY SENATOR WILLIAM PROXMIRE

DEPARTMENTAL MANAGEMENT - PERSONNEL ADMINISTRATION

Question. Last year at this time you were requesting funds to support 890 full-time equivalent in your 1986 personnel administration budget. This year you show a 1986 appropriation for 835 full-time equivalents. Can you explain the sharp drop in staffing below your initial request?

Answer. Our budget requests represent our best estimate, at the time the budget justification is printed, of future staffing and dollar resource needs. Two events occurred in FY 1986 which necessitated a hiring freeze in the Office of the Secretary (OS) and thus a reestimate of full-time equivalent (FTE) employment.

-- The FY 1986 budget justification had a built-in reduction of $3.1 million for the proposed 5 percent pay cut. Although the pay cut was not accepted by the Congress, these funds were not restored to the General Management (OS) appropriation.

-- $3.8 million were reprogrammed from General Departmental Management space renovation and consolidation funds to the Department's AIDS research effort. However, the Office of the Secretary has continued to implement its space reduction plan in order to meet the President's Reform '88 goal and has had to use other salary and expense funds to carry out the effort.

These resource reductions has caused a reestimate of FY 1986 FTE usage for Personnel Administration. Our analysis indicates that due to the resource reductions and the concomitant hiring freeze, the personnel administation function will operate with 6 percent fewer FTE than was estimated one year ago. All critical functions will continue to be performed and we foresee no dimunition in services.

DEPARTMENTAL MANAGEMENT - GENERAL COUNSEL

Question. Last year at this time you were requesting 415 full-time equivalents (FTEs) in your 1986 General Counsel budget. This year you show a 1986 appropriation for 382 FTEs. Can you explain the sharp drop in staffing below your initial request?

Answer. For the same reasons discussed in the previous question (concerning the downward estimate of staffing for personnel administration function) 382 FTEs is our current best estimate of Office of the General Counsel (OGC) FTE usage in FY 1986. Our FY 1986 hiring freeze, brought on by the fiancial reductions discussed above, will cause the OGC to operate at an employment level approximately 8 percent lower than originally planned. As is the case with personnel administration, this reduction in FTE usage by OGC will not offset the performance of control functions.

POLICY RESEARCH

STATEMENT OF ROBERT B. HELMS, PH.D., ACTING ASSISTANT SECRETARY FOR PLANNING AND EVALUATION

ACCOMPANIED BY DENNIS P. WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

BUDGET REQUEST

Senator HARKIN. Our next witness is Robert B. Helms, Acting Assistant Secretary for Planning and Evaluation. Welcome to the committee, Mr. Helms, and please proceed.

Mr. HELMS. I am happy to be here. We are here to discuss the policy research appropriation, which is part of the Office of the Secretary's budget. The requested funding is $5 million which will support research in health, income security, and employment, human services policy. This is $1 million less than the 1986 level, and it reflects the end of the funding of the health insurance experiment which is being conducted. It ran since about 1972, and 1986 is the last year. We will be finished with that big project.

We have shifted from these large multiyear experiments to more emphasis on short-term policy relevant studies. We think that it is a modest investment. We think that it is one worth making. It is a very exciting time, both in the debate on the reform of welfare and also the many changes that have gone on in health policy.

PREPARED STATEMENT

We will submit the testimony for the record, and we will be glad to answer any questions that you might have.

[The statement follows:]

STATEMENT OF ROBERT B. HELMS

I am pleased to be here today to present the fiscal year 1987 budget request for the Policy Research appropriation administered by the Office of the Assistant Secretary for Planning and Evaluation. Policy research provides information for the Congress, the Department, other Federal agencies, states and others on current human resource policies and programs and on the effects of proposed policy changes.

The requested funding of $5 million will support research in health, income security and employment, and human services policy. It is $1 million less than the fiscal year 1986 level. This reduction reflects the end of funding for the Health Insurance Experiment.

Goals and Strategy of the Policy Research Program

As you are well aware, the Department of Health and Human Services is responsible for administering many programs to help meet the Nation's basic health, social service and welfare needs. The Policy Research program is designed to improve our understanding of issues affecting those programs and the problems they are meant to alleviate. It enhances our ability to develop effective policies.

Our research complements the research conducted by HHS's Operating Divisions by focussing on policy issues that cut across organizational and subject lines. It also provides the Secretary with the flexibility to conduct short-term analyses on rapidly arising emerging issues of high priority to the Department.

The broad nature of this program allows us to examine major public policy concerns, such as controlling health care costs, ensuring adequate insurance coverage, reducing long-term welfare dependency, and increasing involvement of the family and the private sector in the delivery of long-term care and other social services.

In recent years we have shifted the focus of the program from large-scale, multi-year experiments (such as the Health Insurance Experiment) to short-term studies. As a result, we are able to respond more quickly to critical information needs of the Secretary, as well as other key decision makers in the Executive and Legislative branches.

I would like to describe briefly key aspects of our proposed research program in three policy areas: Health, Income Security and Employment, and Social Services.

Health Policy Research

Our health policy research will focus on issues associated with improving health care in the nation. Of particular interest are our efforts to enhance the competitive aspects of health care delivery and to fill gaps in coverage for both the underinsured and the uninsured.

By 1987, the prospective payment system for hospitals will have been in place long enough to allow us to examine its effect on the financing and delivery of health services, in particular its impact on physician practice. Our intention is to look at whether the system has changed the patterns of inpatient or ambulatory services provided by physicians. For example, we would like to know to what extent it has increased use of less costly outpatient care.

Another important issue we are examining is how physicians organize for practice and how trends away from hospital practice and toward participation in clinics and health maintenance organizations affect health costs and options for health systems reform. We are also conducting several studies which will examine private sector health benefits for employees and current approaches to treating and paying for uninsured populations.

Taken together, these studies will help us to understand the dynamic change underway in the nation's health care system. We are also hopeful that the research results will provide important insights into ways Medicare may move beyond prospective payment, by purchasing health care competitively for the aged and disabled.

Our preparation of public use data files for the Health Insurance Experiment will be concluded this year. We expect to use the data in 1987 for analysis of a variety of issues related to health financing and tax initiatives. In particular, this information will be useful in examining the effects on patient behavior and health care costs of alternative means of providing coverage for catastrophic illnesses. I expect that this and related research will contribute significantly to Secretary Bowen's response to the President's directive to examine coverage of catastrophic illness.

Income Security and Employment Policy

In the area of income security and employment, we are focusing on two major objectives. First, we continue to seek ways to promote the transition of welfare recipients to self-sufficiency. Second, we are looking

at ways to enhance the role of private savings, insurance, and pensions in providing income to the elderly.

Our efforts directed to promoting the self-sufficiency of welfare recipients focus on increasing private sector employment and child support payments, thereby reducing dependency on public sector programs. This year, we will complete a study of the policy implications of the new AFDC work programs in San Diego, California, Baltimore, Maryland and Arkansas. In all, programs in eleven states will be reviewed. Also, we recently reviewed previous demonstrations and are using this to develop a synthesis of research on long-term welfare dependency and ways to reduce it.

In a joint effort with the Office of Family Assistance, we are beginning a five-year, two-state demonstration to improve the self-sufficiency of teenage mothers with children. The demonstrations are directed toward encouraging these young mothers to complete school, engage in training, seek employment or take other steps toward self sufficiency. In a related effort, we are continuing our investigation of the causes and correlates of inner city poverty and the growth of teenage motherhood.

These and other efforts will contribute materially to our assessment of welfare programs and to the Domestic Policy Council's review of the welfare system.

As a part of our Retirement Policy Studies, we will complete projects that are providing new information on savings behavior, pension entitlements, participation in federal programs, poverty and institutional care. We will continue a study on the economic status of the elderly and will begin a study of disability trends that will enable us to project the size and changing composition of the expanding population of disabled persons and to assess recent reforms in disability programs.

Social Services Policy

Our research on Social Services policy will focus on assessments in two areas: 1) community-based alternatives to institutionalization for the elderly and disabled; and 2) policies which promote family stability.

This year we will complete our evaluation of the National Long Term Care Channeling Demonstration, a ten-state experiment to examine the cost-effectiveness of community-based, long-term care. Findings to date

indicate that the increased availability of case management and formal community services did not reduce the use of hospitals or nursing homes. It did, however, reduce the level of unmet need for care among the elderly, increase their satisfaction with service arrangements and quality of life, and improve the well-being of informal care givers. A final report will be available in May of this year. A study of state approaches to managing long-term care service will also be completed this year. This study documents a variety of state efforts to strengthen community services, while controlling public expenditures.

Our efforts in this area also include an assessment of the impact of the prospective payment system on long-term care. This includes examining its effect on the post-discharge needs and services for individuals with chronic impairments, as well as, the effects on the quality of in-patient and post-hospital care for patients with chronic illnesses.

Our Family Policy research will explore factors in family formation and breakdown, and ways to enhance family support. We will continue our work on foster care and adoption and on an increasing family involvement of teenage fathers. One of Secretary Bowen's priorities is the reduction of adolescent pregnancy. These efforts, along with the project I mentioned earlier on teenage motherhood, will be very helpful in working towards achievement of this important goal.

Conclusion

The Policy Research program is a modest investment. Yet, it provides a ready means to target research on current policy concerns and emerging trends. To a large extent, our program focusses on policies that affect society's most vulnerable people--the poor, the elderly, children, families in crisis and the disabled. Over 50 percent of our project funds support research related to poverty.

In fiscal year 1987, our program can continue to make significant contributions to informing decision-makers on a wide variety of fast changing, difficult and important social policy issues.

Thank you very much.

FISCAL YEAR 1987 BUDGET REQUEST

Senator HARKIN. Again, Mr. Helms, I am going to ask you the same question that I have asked everyone. What was your original budget request for policy research to the Department, and what was the Department's request to OMB?

Mr. HELMS. It was $6 million, and it ended up $5 million.

Senator HARKIN. The Department's request to OMB was what?

Mr. HELMS. It was $6 million.

Senator HARKIN. It was the same as yours.

Mr. HELMS. Right.

Senator HARKIN. OMB cut it by $1 million.

Mr. HELMS. Right, but I would say that we agreed to that. We ended up agreeing that it was reasonable.

GRAMM-RUDMAN REDUCTIONS

Senator HARKIN. Gramm-Rudman sequestering reduces the Office of Policy Research by $280,000. You are also proposing a rescission of $220,000.

What projects will not be funded as a result of the sequestering?

Mr. HELMS. You are really getting to the same question that you have been asking other people. We have looked at the projects and picked out the one, I will go on record, that is our lowest priority, and that is the MRPIS project.

Senator HARKIN. The what?

Mr. HELMS. You are just talking about the 4.3 percent?

Senator HARKIN. I am just talking about the sequestering.

Mr. BRITTEN. Basically, we have a number of broad issue areas, including welfare policy studies, retirement policy, and health care competition. Under the sequester order what we did was to reduce the lower priority projects in those areas. We don't have a specific list of projects because we cut it across the board; we cut down the funding for some of them a little bit.

Senator HARKIN. Were there some that were completely cut out because of the 4.3 percent, or the $280,000 that was cut? Was any project totally not cut, or was there a little bit taken out of a lot of them?

Mr. BRITTEN. The latter, across the board.

Senator HARKIN. You didn't take it all of MRPIS?

Mr. HELMS. No; MRPIS was cut by 4.3 percent, but we also proposed to rescind part of it because, quite frankly, it is our lowest priority project. As a matter of fact, I will go on record as saying that it is inappropriate to be in our budget, and that has been our position for a long time.

We are prepared, however, as the other people have answered today, to go ahead with funding of it after April 16.

Senator HARKIN. Under the sequestering, $280,000, you did not take all of that out of MRPIS.

Mr. HELMS. The reduction in MRPIS is $22,000, or 4.3 percent. Without the rescission they will end up with $478,000.

Senator HARKIN. If there is no rescission, then it will be more.

Mr. HELMS. They would end up with $258,000 if the rescission is approved.

Senator HARKIN. I understand.

I will submit these questions from Senator Proxmire for the record, if you would answer them.

Mr. HELMS. We will be glad to.

SECRETARY'S POLICY RESEARCH PRIORITIES

Senator HARKIN. Incidentally, what are the Secretary's priorities for policy research?

Mr. HELMS. The Secretary has some very definite ideas. The first is that he has a major concern about catastrophic care, and we have a charge from the President to study that. The Secretary has now set up three different working groups, and we are beginning the effort. That report has to be done by the end of the year.

A lot of our effort is to examine some policy research, such as the health insurance experiment, and other work that has been done, and use that information in these different studies of catastrophic care.

The other area that the President has charged us to study is the whole issue of welfare reform. We think that our policy research, the money that has been invested in the last few years, is going to be some of the intellectual basis for that debate. We are working very closely with the Office of Policy Development in the White House on this project. Some of the research is also going into the study of the family under Gary Bauer.

In addition to catastrophic health coverage and welfare reform, the Secretary is concerned about the family, and he is concerned about children, the health of children. We have some projects that relate to, for example, infant mortality, trying to get at the data, to identify where these problems are on a more refined geographical basis.

Senator HARKIN. Anything else, Mr. Helms?

Mr. HELMS. As part of the catastrophic study, the Secretary is concerned about the cost of long-term care; that is one of the three areas that we will study. We have a good bit of research that we have done about long-term care insurance, about the saving patterns of people, and about how the IRA process works. The latter is one of the concepts that has come up—can we use something like an individual medical account, a concept like an IRA, as a possibility for future funding?

We think that our research is going to play a key part in all of this.

Senator HARKIN. Thank you very much, Mr. Helms. We appreciate it.

Mr. HELMS. Thank you.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. We will have some additional questions for response to the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

FY 1987 RESEARCH

Question. In 1978 the budget for your office was $30 million. Your FY 1987 request is $5 million. What kind of research did you sponsor in 1978 that impacted upon the policy of the Department of Health and Human Services?

Answer. A number of the major demonstrations, experiments and data collection efforts ongoing in 1978 have had a continuing impact on the development of policy in the Department. The following are four of the more prominent examples:

The Income Maintenance Experiments consisted of four separate experiments where families were provided cash assistance under one of several benefit and tax formulas. Sites varied in geographical, and demographic characteristics. Findings from the experiments showed the effects of alternative benefits and taxes on work effort, reporting of income, and possibly family stability. This has been important information in restructuring the incentives in AFDC, as well as state and local assistance programs.

The Monthly Income Reporting Demonstrations tested the effects of an automated, monthly, retrospective, client reporting system on benefit savings, administrative cost and feasibility, error rates and responsiveness to recipient need. The demonstrations ran from 1980 to 1982 and the evaluation was completed in 1985. Based on preliminary results from these tests, the initial Colorado pilot demonstration and the experience in the state of California program, retrospective monthly reporting was made mandatory in 1981 for cases with a recent work history or ongoing earned income. While comparisons were made to policies that changed mid-way through the demonstration results do support the soundness and overall payment accuracy of the current policy.

Under the Health Insurance Experiment, 2700 families at six sites were randomly assigned to health insurance plans with differing coinsurance rates and out-of-pocket expenditure limits. The experimental "treatment" lasted from three to five years. The following summarizes the major findings:

Free care substantially increases health care expenditures without a significant improvement in health status for the average healthy person.

Enrollment in an HMO saved about 25 percent compared with free care in the fee-for-service system, due primarily to 40 percent less hospitalization in the HMO.

Free health care resulted in improvements relative to cost sharing, only for persons who began the study with a deficiency in several diagnoses, eg., vision, high blood pressure, or anemia. This evaluation was made on 23 physiological measures. Improvements were concentrated on the bottom 20% of the income distribution.

These findings have had several applications:

Over the past seven years, the experimental data has had a major impact on ASPE'S estimates of the effect of cost sharing on utilization of health services.

Results of the analysis of episodes of treatment and the demand for upplementary insurance provide the basis of the model used to study the effects of Flexible Spending Accounts on health expenditures and tax revenues. The analysis was critical in preparing the report to Congress on this subject.

Well documented public use files ensure heavy use of this valuable data base to analyze a variety of health care cost issues for years to come.

The Panel Study Of Income Dynamics is a longitudinal survey that collects data annually on household income, composition and attitudes, particularly among low income people. This was the first major study to document the dynamic changes in the poverty population and find that far fewer people than previously thought were permanently poor with up to 27 percent of the population falling below the poverty threshhold once over a ten year period: but that a significant fraction of the AFDC recipients are long-term dependent on welfare. The data base produced in this annual survey is used in up to half of our studies done on welfare policy.

AVAILABILITY OF ADDITIONAL RESEARCH MONEY

Question. What could you be doing now if that $30 million was made available?

Answer. It would be exceedingly difficult, perhaps impossible for the Office of the Assistant Secretary for Planning and Evaluation to spend $30 million constructively. There are a variety of reasons for this:

The nature of research activity in this area has changed from the building of basic data bases and conduct of large experiments such as the HIE, the PSID, the Income Maintenance Experiments, and the Survey of Income and Program Participation to conducting smaller, short-term analysis usually using those data. Just as data sources have grown, so has the supply of

researchers and organizations outside of the Federal government capable of quality work in this field.

Total staff in the office was close to 280 FTEs in 1978, but is only 85 today. We would have serious problems overseeing that amount of research.

The role of the Office of the Assistant Secretary for Planning and Evaluation has evolved from that of a major sponsor of large-scale research initiatives, such as those described above, to an office which attempts to use its own funds to ensure that research organizations with ties to those programs address high-priority issues. Examples of this strategy are seen in the evolution of the Panel Study of Income Dynamics. The study was initiated and funded entirely by the Office of Economic Opportunity and then by ASPE through its first ten years, and now is primarily sponsored by the National Science Foundation with an annual contribution of about $200k from ASPE. As another example, we are collaborating with the Office of Family Assistance and private foundations to sponsor and evaluate state demonstrations employing young mothers with young children, as well as evaluating state-run Work/Welfare programs.

HEALTH INSURANCE EXPERIMENT

Question. Briefly summarize the major results of the Health Insurance Experiment.

Answer. Several reports on results from the Health Insurance Experiment have been published in journals and as Rand reports. We will only summarize below a few of the major findings. Well documented public use files were prepared to support additional research on the HIE data in the future. The over 7700 participants in the study at six different sites were representative of the non-institutionalized, non-military, non-aged population.

Persons fully covered for medical services spend substantially more than persons assigned to insurance plans with cost-sharing. For example, persons on the free care plan spend about 45 percent more than those who paid for their initial care up to an income-related limit on out-of-pocket expenditures.

Enrollment in an HMO saved about 25 percent compared with free care in the fee-for-service system. The savings were due primarily to 40 percent less hospitalization in the HMO.

The effect of free care on health status was evaluated with respect to 23 physiological measures, nine health habits, and five indexes of general health outcomes. Free care resulted in improvements relative

to cost sharing only for persons who began the study with a deficiency in vision, high blood pressure or low hemoglobin. Further, the benefits of free care for these three conditions were concentrated primarily among those in the bottom 20 percent of the income distribution. The health status of the initially elevated risk, low income group improved for both the persons assigned to the free plan and the persons assigned to the cost-sharing plans. Those assigned to the free plan improved slightly more. The typical healthy, non-aged enrollee did as well on the cost-sharing plans.

Question. Explain how this data can be used.

Answer. The Health Insurance Experiment has already influenced public and private policy debate and the methods, data and analytical findings from the study can be used to address a number of pro-competitive health care proposals. For the past seven years, all ASPE estimates of the impact of cost sharing on utilization have used parameters developed or critically evaluated by analysts supported by the HIE grant.

Results of the HIE analysis of episodes-of-treatment and the demand for supplementary insurance provide the basis of the model used to study the effects of Flexible Expenditure Accounts on health expenditures and tax revenues. The cost-sharing results have been used in private sector negotiations to increase deductibles in employer-based group health insurance policies. The HMO findings have been cited by advocates of the use of alternative delivery systems.

Under sponsorship of the grant, Rand made major contributions to experimental design, and measurement of health status and quality of care. Variations of the methods developed by Rand to measure health status and health quality could be widely implemented by public agencies and private organizations as a quality assurance mechanism for alternative delivery systems including preferred provider organizations and various competitive, capitation reimbursement arrangements.

The public use files, now in preparation, will provide a data base rich in detail on utilization, expenditures, health status and quality of care. It will be a major source of data for researchers and policy makers for years to come.

Question. Will the findings from this project be of any use in tne new study of catastrophic health coverage?

Answer. The findings could be used to indicate the extent of induced expenditures for various specified

limits on catastrhopic expenditures. However, larger surveys may be necessary to generate more data on catastrophic episodes.

Survey information on family employment, income, assets and debts was collected. The data could be used to examine capacity of families to borrow to finance medical expenditures. In turn, that could help to define means-tested catastrophic expenditure limits and, possibly, to set a policy for subsidized or insured loans for medical expenditures.

Question. Will your office be involved in the catastrophic study?

Answer. Yes, it will.

Question. When can I expect a final report?

Answer. The Secretary has committed to provide the President with a report by year's end.

REFORMS TO THE WELFARE SYSTEM

Question. The President's State of the Union message talked about developing reforms to the welfare system. Who is in charge of this project and is your office involved?

Answer. Because programs designed to help the poor are administered by several government agencies--HHS, HUD, USDA, DoL, Department of Education, etc.-- a wide-ranging view of poverty and family dependency is needed. The President has decided that such a multi-dimensional perspective can come only from a review carried out at the highest level, and has asked the Domestic Policy Council (DPC), on which Secretary Bowen serves, to oversee the study. As Acting Assistant Secretary for Planning and Evaluation, I am an active participant on the DPC working group and expect to be involved in the deliberations leading up to and including the recommendations to be presented to the President in December.

SUBCOMMITTEE RECESS

Senator HARKIN. This concludes our regularly scheduled hearings on the administration's budget request for the Department of Health and Human Services.

The subcommittee will stand in recess until 9:30 a.m., Wednesday, April 9, in 116 Dirksen. At that time, we will begin hearings on the Department of Education, and we will hear from the Secretary of Education, departmental management, salaries, and expenses, Office for Civil Rights, and the inspector general.

[Whereupon, at 11:06 a.m., Wednesday, March 19, the subcommittee was recessed, to reconvene at 9:30 a.m., Tuesday, April 9.]

LIST OF WITNESSES, COMMUNICATIONS, AND PREPARED STATEMENTS

	Page
Alexander, Dr. Duane, Director, National Institute of Child Health and Human Development	723
Biography of	729
Prepared statement	725
Andrews, Hon. Mark, U.S. Senator from North Dakota, questions submitted by	1114
Archer, Loran D., Acting Director, National Institute on Alcohol Abuse and Alcoholism	849
Augustson, Kent, Director, Financial Management, Alcohol, Drug Abuse, and Mental Health Administration	849
Becker, Dr. Edwin D., Associate Director for Research Services, National Institutes of Health	471
Bowen, Hon. Otis R., M.D., Secretary, Office of the Secretary	1
Biography of	21
Prepared statement	8
Bumpers, Hon. Dale, U.S. Senator from Arkansas, questions submitted by	1123
Burdick, Hon. Quentin N., U.S. Senator from North Dakota, questions submitted by	84, 205, 519, 1031
Byrd, Hon. Robert C., U.S. Senator from West Virginia, questions submitted by	844
Chiles, Hon. Lawton, U.S. Senator from Florida, questions submitted by	80, 1120
Crivella, Bart J., Deputy Director for Management and Policy, Office for Civil Rights	771
D'Amato, Hon. Alfonse M., U.S. Senator from New York, questions submitted by	928
Desmarais, Henry, Acting Administrator, Health Care Financing Administration	949
Prepared statement	952
DeVita, Vincent T., Jr., M.D., Director, National Cancer Institute	147
Biography of	152
Prepared statement	148
Doggette, Herbert R., Deputy Commissioner for Operations, Social Security Administration	1033
Domenici, Hon. Pete V., U.S. Senator from New Mexico, questions submitted by	924
Dotson, Betty Lou, Director, Office for Civil Rights	771
Biography of	779
Prepared statement	776
Dunham, Michael, budget officer, Office of Child Support Enforcement	1129
du Buy, Yvonne H., budget officer, National Institute of Allergy and Infectious Diseases	215

Page

Farlee, Dr. Coralie, Assistant Director for Planning and Evaluation, John E. Fogarty International Center for Advanced Study in the Health Sciences 431
Fauci, Anthony S., M.D., Director, National Institute of Allergy and Infectious Diseases 147, 215
Biography of 220
Prepared statement 216
Fitzsimmons, William T., executive officer, National Institute of General Medical Sciences 701
Forbush, Wilford J., Deputy Assistant Secretary for Health Operations and Director, Office of Management, Office of Assistant Secretary for Health 523
Frazier, Dr. Shervert H., Director, National Institute of Mental Health 849, 869
Biography of 876
Prepared statement 872

Gamble, Christopher, Director, Division of Budget, Health Care Financing Administration 949
Goldstein, Dr. Murray, Director, National Institute of Neurological and Communicative Disorders and Stroke 345
Biography of 353
Prepared statement 350
Goldstein, Norman, Director, Office of Management Services, Office of Human Development Services 1153

Hardy, Hon. Dorcas R., Assistant Secretary for Human Development Services, Office of Human Development Services 1153
Biography of 1158
Prepared statement 1155
Harkin, Hon. Tom, U.S. Senator from Iowa, questions submitted by 88
Harris, Robert, Deputy Director for Policy, Programs and Audits, Office of Child Support Enforcement 1129
Hartinger, John P., Financial Manager, National Cancer Institute 147
Hawkes, Phillip N., Director, Office of Refugee Resettlement, Social Security Administration 1033
Biography of 1061
Prepared statement 1055
Hedetniemi, Joel R., executive officer, National Institute of Child Health and Human Development 723
Helms, Robert B., Ph.D., Acting Assistant Secretary for Planning and Evaluation, Policy Research 1243
Prepared statement 1244
Hopkins, John T., Director, Division of the Office of the Secretary Budget Services, Departmental Management 1233

Inouye, Hon. Daniel K., U.S. Senator from Hawaii, questions submitted by 86, 145, 521, 933

Johnson, Elaine N., Acting Deputy Director, National Institution on Drug Abuse 849

Kelso, John H., Acting Administrator, Health Resources and Services Administration 493
Biography of 498
Prepared statement 495
Kirschstein, Dr. Ruth, Director, National Institute of General Medical Sciences 701
Biography of 705
Prepared statement 702
Kupfer, Dr. Carl, Director, National Eye Institute 385
Biography of 389
Prepared statement 386
Kusserow, Richard, inspector general, Office of the Inspector General 747
Prepared statement 755

Page

Laurence, Earl, executive officer, National Institutes of Health 615, 647
Lautenberg, Hon. Frank R., U.S. Senator from New Jersey, questions submitted by 205
Leahy, Hon. Patrick J., U.S. Senator from Vermont, questions submitted by 601
Leasure, Charles E., Jr., executive officer, National Institute of Environmental Health Sciences 409
Lenfant, Dr. Claude, Director, National Heart, Lung, and Blood Institute 669
Biography of 675
Prepared statement 671
Lindberg, Dr. Donald, Director, National Library of Medicine 447
Biography of 453
Prepared statement 449
Little, W. Harell, Chief, Budget Branch, Public Health Service, Office of Assistant Secretary for Health 523
Löe, Dr. Harald, Director, National Institute of Dental Research 313
Biography of 322
Prepared statement 318

Macdonald, Dr. Donald Ian, Acting Assistant Secretary for Health, Office of Assistant Secretary for Health 523
Biography of 530
Prepared statement 524
Mansfield, Norman D., Director, Division of Financial Management, National Institutes of Health 93
Martin, Dr. Edward D., Acting Deputy Administrator, Health Resources and Services Administration 493
Mason, Dr. James O., Director, Centers for Disease Control 783
Biography of 811
Prepared statement 802
Matthews, William, budget officer, National Institute of Neurological and Communicative Disorders and Stroke 345
McClure, Hon. James A., U.S. Senator from Idaho, questions submitted by 1012
McFee, Thomas S., Assistant Secretary for Personnel Administration, Departmental Management 1233
McManus, Edward, Deputy Director, National Eye Institute 385

Nicholas, Edward E., Jr., Acting Associate Director for Administration, Office of the Director 471
Biography of 473
Prepared statement 472

O'Donnell, Dr. James F., Deputy Director, Division of Research Resources 289
O'Shaughnessy, John J., Assistant Secretary for Management and Budget, Departmental Management 1233
Prepared statement 1234

Pickelsimer, Claude F., Jr., Director, Financial Management Office, Centers for Disease Control 783
Pickett, Dr. Betty H., Director, Division of Research Resources 289
Biography of 293
Prepared statement 290
Pittman, James E., Associate Director for St. Elizabeths Hospital Transition, National Institute of Mental Health 869
Prescott, William G., Superintendent, St. Elizabeths Hospital, National Institute of Mental Health 869
Press, Gilbert D., budget officer, National Institute of Dental Research 313
Proxmire, Hon. William, U.S. Senator from Wisconsin, questions submitted by 75, 140, 204, 245, 311, 341, 381, 407, 427, 444, 519, 596, 667, 697, 721, 745, 767, 781, 836, 931, 1015, 1116, 1149, 1201, 1241

Page

Rall, Dr. David P., Director, National Institute of Environmental Health Sciences ... 409
Biography of ... 413
Prepared statement ... 410
Raub, Dr. William F., Deputy Director for Extramural Research and Training, National Institutes of Health ... 93
Renault, Dr. Pierre, Acting Director, National Institute of Diabetes, and Digestive and Kidney Diseases ... 615
Biography of ... 621
Prepared statement ... 617
Ritchie, Steve, Director, Office of Child Support Enforcement ... 1129
Biography of ... 1136
Prepared statement ... 1131
Ross, Jo Anne B., Associate Commissioner for Family Assistance, Social Security Administration ... 1033
Ross, Karyn S., budget officer, National Institute on Aging ... 247
Rudman, Hon. Warren D., U.S. Senator from New Hampshire, questions submitted by ... 69

Sabatini, Nelson J., Acting Deputy Commissioner for Management and Assessment, and Associate Commissioner for Management, Budget and Personnel, Social Security Administration ... 1033
Biography of ... 1060
Prepared statement ... 1034
Shulman, Dr. Lawrence, Acting Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases ... 647
Biography of ... 652
Prepared statement ... 648
Smith, Kent A., Deputy Director, National Library of Medicine ... 447
Specter, Hon. Arlen, U.S. Senator from Pennsylvania, questions submitted by ... 72, 139, 286, 310, 340, 518, 595, 923, 1010, 1200, 1225
Speers, Jerrold B., Director, Office of Community Services ... 1207
Prepared statement ... 1211
Stevens, Hon. Ted, U.S. Senator from Alaska, questions submitted by ... 594, 1008

Trachtenberg, Robert L., Acting Administrator, Alcohol, Drug Abuse, and Mental Health Administration ... 849
Biography of ... 857
Prepared statement ... 850

Wallace, Dr. Craig K., Director, John E. Fogarty International Center for Advanced Study in the Health Sciences ... 431
Biography of ... 435
Prepared statement ... 432
Walsh, James A., Associate Administrator for Operations and Management, Health Resources and Services Administration ... 493
Whaley, Storm, Associate Director for Communications, National Institutes of Health ... 471
Prepared statement ... 473
Williams, Dennis P., Acting Deputy Assistant Secretary, Budget, Department of Health and Human Services ... 93, 289, 313, 949, 1033, 1129, 1153, 1243
Williams, Dr. T. Franklin, Director, National Institute on Aging ... 247
Biography of ... 261
Prepared statement ... 257
Wyngaarden, Dr. James, Director, National Institutes of Health ... 93, 147, 215, 247, 289, 313, 345, 385, 409, 431, 447, 471, 611
Prepared statement ... 98

SUBJECT INDEX

DEPARTMENT OF HEALTH AND HUMAN SERVICES

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

	Page
Alcohol, drug abuse, and mental health:	
Block grant	864
Research, funding for	860
Alcoholism	866
Alzheimer's disease	865
Budget cuts, research affected by	867
Community support program	862
Protection and advocacy	861
Questions submitted by the subcommittee	877
Research training	867
St. Elizabeths Hospital:	
Hiring freeze	870
Patient death	869
Teenage suicide	864

CENTERS FOR DISEASE CONTROL

Budget request, FTE reduction from	787
Budget submission, original	788
Immunization, childhood	789
Questions submitted by the subcommittee	813

DEPARTMENTAL MANAGEMENT

Appropriation request	1235
Debt collection target	1237
Delinquency reductions in fiscal year 1986	1237
Gramm-Rudman reductions	1236
Questions submitted by the subcommittee	1238
Regional office study	1236

HEALTH CARE FINANCING ADMINISTRATION

Budget request:	
Fiscal year 1987	962
Formulation of fiscal year 1987	958
Highlights of fiscal year 1987	949
Bypass, extracranial/intercranial	961
Coordinating councils, end-stage renal disease network	951
Costs, administrative	951
End-stage renal disease network:	
Coordinating councils, reduced number of	966
Plans for	967
Gramm-Rudman-Hollings	951
Health care trust funds, payments to	950

Page

Intermediate care facilities for the mentally retarded vocational and education costs, disallowance of 964
Medicaid 950
Cap, proposed 958
Medicare:
Claims processing, delays in 965
Contractors 950
Payment cycle 961
Part B payments, rounding of 960
Plasmapheresis, coverage of 962
Program management 950
Questions submitted by the subcommittee 968
Research 950
Second surgical opinions, mandatory 958
Staffing reduction 964
Survey and certification (Medicare) 950
Survey, Cornell Medical Center 960
Surveys, hospice 966

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Block grant, primary care 509
Budget:
Advocacy 509
Defense of 505
Initiative 502
Community Health Center 508
Base grants 503
Default cases, National Health Service Corps scholarship 506
Default rate 504
Field strength, National Health Service Corps 506
Geriatric academic units 505
Geriatric medicine, training teachers in 501
Geriatric training:
Initiative 499
Personnel needed for 501
Health education assistance loans 504, 508
Health maintenance organizations 507
Nurse training 509
Public Health Service, request from 499
Questions submitted by the subcommittee 511
Resources, redirection of 502

NATIONAL INSTITUTES OF HEALTH

Acquired immune deficiency syndrome centralization 110
Advances, research 94
Awareness, public 106
Budget request:
Chronology of 102
Development of 111
Fiscal year 1987 96
Budget, adjustments in fiscal year 1986 95
Centennial:
Celebration of 108
National Institutes of Health 94, 106
Construction 612
Employment 612

Page

Grants:
- Biomedical research support ... 111
- Funding of ... 611
- Research ... 611
  - Project ... 108

Health care costs, savings in ... 95
Indirect costs, proposed cap on ... 112
Intramural research ... 612
Pertussis vaccine ... 613
Priorities, budget ... 106
Public relations ... 107
Questions submitted by the subcommittee ... 112
Request, presentation of ... 94
Staffing at ... 109

DIVISION OF RESEARCH RESOURCES

American Association for the Accreditation of Laboratory Animal Care ... 296
Animal welfare assurances ... 295
Indirect cost freeze, impact of on institutions ... 297
Questions submitted by the subcommittee ... 298
Radon gas, research related to ... 298
Reduction, 1987 proposed ... 298

JOHN E. FOGARTY INTERNATIONAL CVENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES

Questions submitted by the subcommittee ... 439
Romanian cancer scientists ... 438

NATIONAL CANCER INSTITUTE

Achievements, major scientific of past year ... 156
Acquired immune deficiency syndrome research:
- Drug:
  - Development ... 162
  - Testing ... 159
  - Treatment ... 162
- Education ... 161
- Fatality rate ... 160
- Funding ... 159
- Heterosexual transmission ... 164
- Number of victims ... 159
- Patient care ... 161
- Progress in ... 157
- Protection of number of victims ... 164
- Vaccine ... 163

Basic biology, investment in ... 171
Breast cancer treatment, clinical trial of ... 170
Cancer cells, molecular characterization of ... 156
Cells, Interleukin-2 and LAK ... 175
Data system, international food composition ... 171
Diet and nutrition ... 169
Foods, healthier ... 174
Formaldehyde study ... 168
Funds, reduction of ... 170
Prevention awareness program ... 173
Questions submitted by the subcommittee ... 177
Resources, reprogramming ... 176
Salary levels ... 166

Page

Sequestration and rescission 165
Studies, human nutrition 172

NATIONAL EYE INSTITUTE

Clinical trials 390
Infections, corneal 391
Laser treatment 392
Questions submitted by the subcommittee 392

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Acquired immune deficiency syndrome 670
Funding 677
Clinical trials 677
Cystic fibrosis 669
Drugs, clot-dissolving 669
Flexibility, fiscal 676
Nobel Prize recipients 669
Program balance 679
Questions submitted by the subcommittee 679
Risk, coffee and heart disease 678
Sickle cell disease 670

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Advances, other important 224
Cuts, budget 225
Questions submitted by the subcommittee 226
Vaccine trial, acellular pertussis 225
Vaccine, malaria 224

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

Questions submitted by the subcommittee 658

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Acquired immune deficiency syndrome 730
Adolescent suicide 730
Birth defects 723
Budget:
Chronology, fiscal year 1987 731
Reductions, impact of 732
Request, fiscal year 1987 724
Coordination with Dr. Nickens 731
Infant mortality, reducing 723
Inhibin 724
Injuries, childhood 724
Low birth weight initiative 731
Mental retardation 724
Questions submitted by the subcommittee 734
Sudden infant death syndrome 723

NATIONAL INSTITUTE OF DENTAL RESEARCH

Acquired immune deficiency syndrome research 316
Anticaries vaccine 314
Antiplaque agents 315
Questions submitted by the subcommittee 316
Vaccine, herpes 315

NATIONAL INSTITUTE OF DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

	Page
Arthritis Institute, new	628
Clinical trials	622
Cystic fibrosis	628
Diabetes control and complications trial	628
End-stage renal disease	629
Juvenile diabetes	624
Cost of research into	625
Nutrition:	
Coordinating committee	631
Program	629
Training in	631
Questions submitted by the subcommittee	632
Reprogramming	622
Transplantation, islet cell	622

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Air pollution, indoor	418
Asbestos in drinking water	415
Chemicals	418
In animal feed	419
Clinical trials	415
Dioxin	415
Drugs, inadequately tested	415
Environmental problems	419
Methylene chloride	414
Polychlorinated biphenyls	416
In mother's milk	415
Quality assurance	420
Questions submitted by the subcommittee	421
Radon	417
Testing program	420
Toxicity	415
Combination	420

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Budgets, comparison of National Institute of General Medical Sciences and National Science Foundation	708
Clinical trials	709
Questions submitted by the subcommittee	711
Research project grants, effects of emphasis on	709

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

Acquired immune deficiency syndrome dementia	348
Alzheimer disease	364
Approvals, clinical trial	365
Budget requests, Institute	354
Budgetary evaluations, science	366
Clinical trials	359
National Institutes of Health	360
National Institute of Neurological and Communicative Disorders and Stroke	358
Development program, orphan drug	358
Extracranial/intracranial anastamosis	346
Function, restitution of	347
Implants, brain cell	348

Page

Injury, head and spinal cord 367
Javits, Senator Jacob 345
Program reductions, Institute 358
Questions submitted by the subcommittee 368

NATIONAL INSTITUTE ON AGING

Alzheimer disease 248
  Centers 253
  Costs 253, 255
Areas, high priority 249
Budget request 249
Diagnosis, Alzheimer disease 254
Life expectancy 250, 252
Population, older 252
Questions submitted by the subcommittee 256
Stress, care-giver 255
Training 251

NATIONAL LIBRARY OF MEDICINE

Network, regional medical library 455
Questions submitted by the subcommittee 457
Services:
  Demand for 456
  Library 455
Sesquicentennial 456

OFFICE OF DIRECTOR AND BUILDINGS AND FACILITIES

Budget request 478
Questions submitted by the subcommittee 484

OFFICE FOR CIVIL RIGHTS

Attorneys, need for 774
Constituent groups 774
Discrimination complaints 773
Enforcement cases 773
Grove City College decision 772
Outreach program 774
Questions submitted by the subcommittee 780
Section 504 regulation 771
Staff, legal services 772

OFFICE OF CHILD SUPPORT ENFORCEMENT

Child support payments 1137
Questions submitted by the subcommittee 1139

OFFICE OF HUMAN DEVELOPMENT SERVICES

Aging nutrition support 1175
Budget request to:
  Department 1160
  Office of Management and Budget 1160
Categorical funding recommendations 1161
Challenge grants 1166
Developmental disabilities 1168
Elderly abuse 1163
  Projects, funding 1164

Page

Elderly, local services for ... 1169
Employment-related activities ... 1169
Family:
  Crisis proposal ... 1162
  Violence ... 1162
Fiscal year 1987 request, compared to 1986 ... 1167
Head Start ... 1173
Legal services:
  Activities ... 1171
  In Iowa ... 1172
  Level of funding for ... 1173
Prerescission versus postrescission ... 1168
Pro bono services ... 1171
Program request, consolidated ... 1166
Project proposals, quality of ... 1164
Projects, funding ... 1165
Questions submitted by the subcommittee ... 1176
Requests to Department and Office of Management and Budget ... 1168
Rescission proposals ... 1161
Special handicapped projects, 1986 support for ... 1173

OFFICE OF COMMUNITY SERVICES

Budget request ... 1207
Community services block grant, termination of ... 1207
Program duplication ... 1208
Questions submitted by the subcommittee ... 1217

OFFICE OF REFUGEE RESETTLEMENT

Budget, fiscal year 1987 ... 1068
Opening remarks on ... 1064
Refugees ... 1064

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

Acquired immune deficiency syndrome:
  Allocation of funding for ... 547
  Funding, centralization of ... 531
Activities, coordination of ... 535
Administrative oversight, concerns regarding ... 533
Adolescent family life ... 546
Assistant Secretary for Health, support from ... 534
Budget constraints, possible ... 536
Constituent support ... 540
Infant mortality:
  Black ... 542
  Increased funding for ... 544
Minority health ... 545
National Center for Health Statistics ... 543
Questions submitted by the subcommittee ... 550
Rural health, workshop on ... 541
Staff reassignments and program costs ... 538
Teenagers, sexually active ... 547
User liaison program ... 536, 541
Workshop program, cost of ... 539

OFFICE OF THE INSPECTOR GENERAL

Page

Costs, office space ... 752
Early discharges ... 750
  Reasons for ... 750
Federal buildings:
  Office space in ... 753
  Rent increases ... 754
Reorganization of ... 753
Prospective Payment Commission ... 751
Prospective payment system ... 749
Questions submitted by the subcommittee ... 757
Staff cuts, sustaining savings during ... 748
Trust funds, charges to ... 752

OFFICE OF THE SECRETARY

Acquired immune deficiency syndrome ... 4
  Victims:
    Direct care ... 40
    Help for ... 40
Action, corrective ... 38
Bid, competitive ... 39
Biomedical research ... 4
Budgets, disparity between National Science Foundation and National Institutes of Health ... 44
Catastrophic illness coverage ... 4
Children ... 5
Clarification, Gramm-Rudman-Hollings ... 37
Congress:
  Intent of ... 32
  Quick response to ... 24
Contract, award of ... 38
Costs, rural hospital and physician ... 36
Cuts:
  National Institutes of Health ... 41
  National Science Foundation/National Institutes of Health budget ... 45
Elderly abuse ... 32
Families ... 6
Good Samaritan-Linfield School of Nursing ... 22
Health costs, control of ... 3
Health Resources and Services Administration ... 33
Health, minority ... 31
High-risk groups ... 30
Infant mortality ... 29
Massachusetts Blue Cross/Blue Shield ... 37
Medical practice, costs of ... 35
Minorities and scholarships ... 34
Nursing Research, National Center for ... 45
Older Americans ... 6
Out years, effect in ... 27
Prenatal care ... 30
Priorities, Gramm-Rudman-Hollings ... 26
Programs:
  Entitlement/discretionary ... 25
  Human services ... 5
Questions submitted by the subcommittee ... 47
Reductions, health ... 28
Research grants, National Institutes of Health ... 23

Page

Research projects, reduction in 24
Scientists, pool of 23
Senator Chiles, welcome from 29
Services, protection and advocacy 42
Subcommittee, working relationship with 22
Underserved areas 33
Work force, research 25

POLICY RESEARCH

Budget request 1243, 1248
Gramm-Rudman reductions 1248
Questions submitted by the subcommittee 1250
Secretary's policy research priorities 1249

SOCIAL SECURITY ADMINISTRATION

Beneficiary population, service to a growing 1066
Deferral request, explanation of 1070
Disallowances, aid to families with dependent children 1067
Elderly, effect of budget reductions on 1069
Full-time equivalent reduction plan, update on long-term 1071
Gramm-Rudman 1063
Questions submitted by the subcommittee 1073
Senator Specter's letters, response to 1064
Service to the public, General Accounting Office report on 1067
Staff reductions, long-term 1065
Staffing cuts, concern over 1069
Systems modernization plan, slippage in 1072

O